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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA I-61

TITLE: Technical Support for the National Center for Environmental Research's (NCER) Human Health Team

NOTE: Some work appearing herein is expected to take place outside of the period of performance (PoP) of this option year, and as such is included for informational purposes only to give context to the entire project. While the work plan may discuss technical details as needed on these items occurring outside the PoP, the cost estimate should only include expected cost incurable

Specify Section & Paragraph SOW:

E1, Risk Assessment Support; Science Writing, Risk Communication and Training E2, Risk Assessment Support; Administration and Technical Support for Meetings

PERIOD OF PERFORMANCE: CO award to 10/31/15

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) Human Health Research Program of the National Center for Environmental Research (NCER) for administrative and technical support to maximize the utility of the extramural research that it funds. The contractor shall only perform those activities herein as initiated by the EPA WA COR through Technical Directives. At times the contractor shall need to directly contact the Principal Investigators (i.e., the extramural researchers) or members of the Human Health Research Program to either collect additional information or to clarify information.

Under this work assignment, the contractor shall:

- (1) Provide technical, information transfer, communications and logistical support for program, and progress review workshops, EPA and ORD science meetings involving its investigator initiated research grants, as well as other meetings and workshops supported by NCER management.
- (2) Assist the Human Health Team in developing synthesis reports to summarize research across all projects within a single RFA; across multiple RFAs within a single research area; or across all research areas. The Human Health Research Program is categorized into several Research Areas (e.g. Children's Health, Tribal Health, Computational Toxicology, Cumulative Risk). For the purposes of this work assignment, this deliverable is called the Human Health Synthesis Reports.

II. BACKGROUND

NCER's Human Health Research Program seeks to promote extramural research as part of the Science to Achieve Results (STAR) program that will enhance scientific knowledge about the various ways that environmental pollutants adversely affect public health and the environment. Given EPA's critical mission of protecting human health – as well as the rapid emergence of research using new scientific understanding and technologies – the Human Health Team is well positioned to play a pivotal role in aggregating, synthesizing and

publicizing the findings of funded research. The research generates findings related to environmental health risks and issues and multiple sources of environmental stressors. Such findings contribute to a better characterize complex exposures and/or risk from multiple stressors (e.g., environmental, socio-economic), sources and routes that influence human health outcomes, highlighting health concerns pertaining to children's environmental health, cumulative risk and environmental justice, among other Agency priorities.

Under this work assignment, the contractor shall:

a) Arrange the 2015 Children's Centers meeting during the week of October 26th in Washington DC, jointly held with the Pediatric Environmental Health Specialty Units (PEHSUs). The meeting will be held over three days. Approximately 70 participants are expected to attend the first day. This will be followed by a two-day meeting for approximately 200 participants. The purpose of the annual Children's Centers meeting is to bring together researchers, clinicians, scientists and representatives of professional organizations and other participants will convene to explore the interplay between research, clinical applications, and policy implications in children's environmental health.

EPA's Office of Research and Development, EPA's Office of Children's Health Protection, and the National Institute of Environmental Health Sciences (NIEHS) are sponsoring this conference to celebrate the work of the EPA/NIEHS Children's Centers program and to discuss recent developments in children's environmental health.

The meeting will feature interdisciplinary presentations and discussions that explore connections between research findings, clinical and community practice, how to reduce risk and protect children from harmful environmental exposures and discuss approaches for sharing research findings and technical information with the scientific community, parents and the public.

b) Prepare a synthesis report summarizing key successes and findings from the EPA/NIEHS Children's Centers Program that has been jointly funded for more than 16 years. The research conducted under this program covers the entire environmental health paradigm from exposure to health effects, risk assessment, and to managing those risks, including community outreach, engagement and translation. The report will be approximately 30-40 pages, and build on the report: A Decade of Children's Environmental Health Research (http://www.epa.gov/ncer/publications/research_results_synthesis/ceh_report_508.pdf). The contractor should use creative methods for conveying research findings and progress such as in the summary "Celebrating 25 Years of the Superfund Program"

(http://www.niehs.nih.gov/research/supported/assets/docs/r_s/srp_25th_anniversary_commemorative_b ooklet_508.pdf).

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The

Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in administrative and technical support to a conference. The contractor shall prepare a QAPP describing the necessary QA procedures, quality control activities and other technical activities that will be implemented to ensure that the synthesis report is factually correct, that any interpretation of results or findings are accurate and that the report is prepared to the highest quality.

Task 3: PRE-CONFERENCE PREPARATION

Task 3.1. Conference Location

The contractor will identify meeting rooms in Washington DC for hosting the three day meeting and include approximately 70 sleeping rooms at government per diem rates. The facility would need to have space for a poster session area (approximately 20 posters) on days 2 and 3. Two Breakout rooms would be needed for days and 3. The contractor shall provide the list of available locations to EPA for approval and arrange visits to the locations that are best suited for the meeting. When selecting the meeting location, the contractor will consider proximity to the Metro and other characteristics that would be suitable for visitors.

Task 3.2. Conference website

The contractor shall setup a website similar to the 2013 Children's Centers website (http://www.scgcorp.com/PCH2013/index.asp) providing information regarding the meeting, agenda, logistics (such as directions to the meeting location, hotel accommodations, transportation, parking and dining options), speaker bios, and poster and session abstract submission, and registration tabs.

The Contractor shall receive poster and session abstracts following the initial call for abstracts by the conference organizers. The Contractor shall compile received abstract titles and prepare a spreadsheet to facilitate Steering Committee review of abstracts and placement in the conference program following acceptance of the posters and presentations.

Registration: The registration tab will collect typical registration information and include obtaining information on which part of the contact information can be made available to (a) other registrants of the conference and (b) the general public as part of the post conference report.

The Contractor shall provide a spreadsheet of pre-registrants 4 weeks prior to the conference, and again beginning each week thereafter until the start of the conference, unless there were no new pre-registrants added during that period.

Task 3.3. Other Pre-Meeting Logistical Activities (e.g. Coordination with speakers, securing on-site Audio/Visual, IT support):

The Contractor shall, when provided with a list of potential speakers and moderators obtain signed release forms for presentations by all speakers for both upload onto an ftp site and for publication in the conference report, obtain their appropriate power point presentations and organize these presentations in an appropriate matter to be ready to load onto computers at the conference. The Contractor shall also provide other necessary logistical support for presenters and attendees and coordination of presentation materials.

The Contractor shall arrange AV support and ensure that proper AV equipment is available (microphones, laptops and projectors). The Contractor shall serve as the lead point of contact to insure the adequate flow of all activities on the days of the conference and coordinate the speakers and overall participation of other representatives.

The Contractor shall be available for on-site registration as necessary, provide any copies of relevant meeting material and allow sufficient space at the entry table for speakers and participants to leave relevant information for pick-up at the time of on-site registration. The Contractor shall coordinate registration near the main meeting room.

Task 3.4. Preparing Conference Materials:

The Contractor shall prepare information materials in a conference Information Packet. The packet shall include announcements and a final conference agenda. The Contractor shall provide a list of overall participants and presenters, their contact information, and Bios of presenters. The Contractor shall include this information in a Conference Information Packet and make these packets available in sufficient numbers to provide each participant with a packet at the time of on-site registration.

TASK 4: DURING-CONFERENCE RESPONSIBILITIES

Task 4.1. Conference Registration:

The on-site Contractor support shall include manning the registration table, providing participant name tags and conference information packets, name tents for speakers. Ensure adequate directional meetings signs to assist attendees to the meeting/registration areas.

Task 4.2. Conference IT Logistics:

The Contractor shall coordinate with the facility AV staff to ensure that all AV equipment have been provided and presentations are loaded onto computer. EPA can provide laptop if it would save costs.

Task 4.3. Note Taking

The contractor shall take notes during all sessions for preparing proceedings from the meeting.

Task 4.4. Meeting Evaluation Summary

The contractor shall distribute the meeting evaluation form and collect on the last day of the meeting.

TASK 5: POST-CONFERENCE

Task 5.1. Conference Proceedings:

The Contractor shall prepare conference proceedings to include a table of contents, agenda, meeting summary including speaker question and answer sessions, speaker biosketches, poster abstracts, a complete list of actual attendees and their contact information as agreed upon during the registration process.

Task 5.3 Meeting Evaluation Summary

The contractor shall compile the comments and prepare an evaluation summary.

Task 5.2. Power Point Presentations:

The Contractor shall post the released presentations onto an ftp site that can be accessed by the conference participants.

TASK 6: HUMAN HEALTH SYNTHESIS REPORTS

Human Health Synthesis Reports Contractor will assist the Human Health Research Program in developing and drafting reports and short research summaries with graphics (e.g. one page flyers, fact sheets pamphlets and brochures) to synthesize the extramural research funded by the Team. Contractors may be asked to assist in

developing a synthesis report and short summaries to summarize research across all Projects within a single RFA; across multiple RFAs within a single Research Area; or across all Research Areas.

Task 6.1. Synthesis report - EPA/NIEHS Children's Centers Program - 15 years of success

The contractor shall prepare the 15 year synthesis report summarizing key successes and findings from the EPA/NIEHS Children's Centers Program that has been jointly funded for more than 16 years. EPA will provide to the contractor results from research on successes from the Centers conducted by NIEHS that may guide how this document is formulated. A work group is being formed which includes Children's Centers Directors and staff, EPA and NIEHS program and other staff such as the Communications Department to further help identify the key areas of focus and to assist in collection of materials needed.

To write a report at the high level of quality needed, the effort will require staff with education backgrounds at both PhD and Master's degree levels with expertise in public and/or environmental health.

Staff at the PhD level will need to evaluate the important research results and their potential significance for achieving outcomes in the years to come. It may be necessary to utilize outside resources to evaluate the impact of the Children's Centers program. Staff at the Master's degree level will review grants reports, and other materials supplied by EPA, draft the summary, review comments and finalize the report.

The contractor shall:

- a) Review materials provided by EPA and prepare a proposed draft outline
- b) Arrange/participate in the synthesis report workgroup call and prepare action items from the calls
- c) Assist the workgroup define the parameters for the report and help identify creative methods for sharing data, findings and other information.
- d) Prepare revised outline and review with EPA and workgroup members
- e) Where necessary, contact current and previously funded Children's Centers to collect information identified by the workgroup.
- f) Prepare synthesis report based on revised outline.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., MS Office 2010 (or later) spreadsheets and documents.

V. DELIVERABLES AND SCHEDULE

Task 1.	Initial conference call	3 days after award of Work Assignment
Task 2.	Work and Staffing Plan	20 days after award
	QAPP	4 weeks after award
Task 3.	Conference location	2 weeks after award
	Conference website	2-3 weeks after award
	List of Poster Abstracts	4 weeks prior to conference and weekly up to conference
	List of Registrants	date
	Conference Information Packets	October 13, 2015
Task 4.	Conference Materials	October 14, 2015

Task 5.	Evaluation Summary	Within 2 weeks of conference conclusion
	Draft Conference Proceedings	Within 3 weeks of conference conclusion
	Final Conference Proceedings	Within 20 business days after receipts EPA comments
Task 6.	Participate in workgroup calls	As arranged
	Proposed outline	Within two weeks of receiving materials
	Collect materials from Centers	4 weeks
	Revised outline	2 weeks after all materials collected
	First Draft of report	6 weeks after outline approved
	Second Draft of report	Within 2 weeks of NCER approval and comments
	Third Draft Laid out	Within 2 weeks of NCER approval and comments
	Final Review Draft	Within 2 weeks of NCER approval and comments
	Final Report	Three weeks after receiving NCER approval

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Nica Louie U.S. EPA/ORD/NCER 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460 Telephone: 703-347-8125

Alternate WAM:

Cynthia Nolt-Helms (703) 347 8102 Nolt-helms.cynthia@epa.gov

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA I-61 Amend 1

TITLE: Technical Support for the National Center for Environmental Research's (NCER) Human Health Team

This amendment is to add the following task:

Task 3: PRE-CONFERENCE PREPARATION

3.4 The Contractor shall provide support in pre-meeting calls with the Conference Steering Committee and agenda development. This includes minutes from steering committee conference calls, revising the agenda and list of topics, following up with proposed speakers, obtaining session titles, abstracts, and biosketches for speakers, assisting in reviewing abstracts submitted and selecting sessions and posters.

Deliverable:

- 1. Minutes from calls within one or two business days
- 2. Revised agenda/topics
- 3. Following up with proposed speakers/poster presenters

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 1-62

TITLE: Technical Support for the Development of an In Vivo Point of Departure Database

Sections and Paragraphs of Contract SOW: C.1

PERIOD OF PERFORMANCE: CO approval/issuance through October 31, 2015

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide services to the U.S. Environmental Protection Agency's (hereinafter, EPA) National Center for Environmental Assessment (NCEA) and National Center for Computational Toxicology (NCCT), within the Office of Research and Development (ORD). The specific purpose is to provide technical support for the development of a database of curated in vivo point of departure (POD) values for a diverse set of oral noncancer and cancer endpoints as identified in the contract performance work statement, Section C.1. The majority of work is expected to consist of study quality evaluation and doseresponse analyses supporting the identification of study-level lowest-observed-adverse-effect level (LOAEL) values for many toxicity studies associated with several different chemicals. Data QA and data management will also be a part of the tasks in this WA.

II. BACKGROUND

Over the past four decades, EPA has made significant progress in protecting human health and the environment from the adverse effects of chemical exposures. The tens of thousands of chemicals in the environment, however, are overwhelming our ability to evaluate their safety using traditional approaches. Cognizant of this impediment, the release of the National Research Council's Report "Toxicity Testing in the 21st Century: A Vision and a Strategy" (NRC, 2007) initiated a broad-based movement in the toxicology community to reassess how toxicity testing and risk assessment are performed. Several studies have been conducted over the past five years that together may contribute first steps toward executing the shared vision, and these studies were recently assembled into a data-driven framework that invokes successive tiers of toxicity testing (Thomas et al., 2013).

In a collaborative effort between EPA's NCEA and NCCT, projects are currently under way with respect to the first tier of the aforementioned tiered framework. In one such project, the general approach is to develop a database that collates in vivo POD values in a semi-standardized way from multiple data sources. The database will ultimately be used in future proof-of-concept evaluations as the basis for comparison with POD values estimated using data from multiple high-throughput approaches/methods including physicochemical structure and in vitro assays. This WA supports the development of this in vivo POD database.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within three (3) days of start date of this WA, the Contractor shall schedule a kick-off conference call (not to exceed 2 hours) with the EPA Work Assignment Manager (WAM) and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan (submitted as part of the Work Plan) that shows assigned personnel by task and the qualifications of the proposed personnel. At a minimum, major contributors in this WA are expected to be Professional Level 4 or 3 and have expertise in the areas of toxicology and human health risk assessment. Personnel with additional training and certifications (e.g., DABT) are highly recommended. Contract staffing with previous experience in developing health assessment documents for the U.S. EPA and a thorough familiarity with EPA guidance utilized for performing health assessments is highly desired. Additionally, the contractor shall provide personnel who are highly proficient with the software tools Microsoft Access and Microsoft Excel. Additionally, personnel proficient in MySQL is preferred but not required.

The Contractor shall also develop a QAPP for approval by the WAM and Quality Assurance Manager. See these documents: "EPA Manual C/O 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)" and "EPA Requirements for Quality Assurance Project Plans (QA/R-5)." The QAPP shall be submitted simultaneously with the Work Plan for approval. The Contractor shall not perform any work on subsequent tasks under this PWS until the Work Plan and QAPP are reviewed and approved. If the WAM determines that the final Work and Staffing Plan is inadequate, the Contractor will have ten (10) days to submit substitute staff for review and approval by the WAM.

Task 3: Study Quality Evaluation

EPA will provide the Contractor with the decided upon format by which study data to be analyzed will be submitted. It will likely be outputted database files in the form of Microsoft Excel Comma Separated Values Files or standard Excel spreadsheets (one file per study) that will contain a study's design and treatment group information as well as the observed treatment-related effects (see Attachment 1A and 1B as examples of how study data may be presented; note that delivery logistics of the final files submitted to the Contractor will require discussion at the kick-off conference call [Task 1 above]). The edited/amended versions of these files will ultimately be reintegrated into the MYSQL version of ToxRefDB and eventually combined with data from other sources into an in vivo POD database. Attachment 2 of this WA is a README file that will assist the Contractor in the proper interpretation of the data and performing the tasks within this WA. Files of all studies (primarily in PDF format) will also be provided to the Contractor using a standardized file naming convention. TIFF, Word, and Word Perfect are other potential file formats the studies may be provided as.

In Task 3, the Contractor shall perform a study quality evaluation for all studies identified as "open_lit" in the "study_source" (or "data_source") field (roughly 500 total studies). In order to provide direction and suggest ways to evaluate and document study quality, Attachment 3 of this WA provides a list of questions relating to study features that should be considered when evaluating in vivo animal toxicology studies, namely: exposure, test animals, study design, toxicity endpoints, data presentation and statistics, as well as the reporting of this information. By no means are these questions comprehensive and, for most studies and endpoints, some of

these questions may not be applicable. EPA and OECD guidelines can be consulted for recommendations on the design and interpretation of toxicology experiments. The Contractor shall provide transparent documentation of the evaluation of "open_lit" study quality on a study-by-study basis via the "study_comment" field in the edited/amended database deliverables.

Task 4: Identification of Critical Effect(s) and Establishment of Study-Level Lowest-Observed-Adverse-Effect Level (LOAEL) Values

The noncancer effects listed in the "effect_type", "effect_target", and "effects_desc" fields have been previously determined to be treatment-related and statistically and/or biologically significant. An example of an effect type, target, and description would be pathology, liver, and hypertrophy, respectively. In Task 4, from all previously identified treatment-related effects, the Contractor shall use expert judgment to identify the critical effect(s) to establish study-level LOAEL values on a study-by-study basis for roughly 2,500 specific studies. The critical effect(s) used to identify the study-level LOAEL shall be denoted by "checking" the box of the Boolean (yes/no) "critical effect" field in the edited/amended database deliverables. "NULL" value entries for a given treatment group indicate that no treatment-related effects were observed. A brief rationale/narrative regarding the choice of the critical effect(s) and establishment of the study-level LOAEL value shall be provided in the "dose_comment" field on a study-by-study basis. Additionally, in the process of determining the critical effect(s) to establish study-level LOAEL values, any remarks on the treatment-relatedness of the observed effects (previously determined) should be documented in the "effect_comment" field.

For all multigeneration reproductive toxicity studies (denoted as "MGR") identified in the "study_type" field, treatment-related effects were further identified as either a "Parental", "Reproductive", or "Offspring" effect category. Thus, "Parental", "Reproductive", and "Offspring" study-level LOAEL values should be identified whenever applicable on a study-by-study basis. Similarly, for all prenatal developmental toxicity studies (denoted as "DEV") in the "study_type" field, treatment-related effects were further identified as either a "Maternal" or "Developmental" effect. Thus, "Maternal" and "Developmental" study-level LOAEL values should be identified whenever applicable on a study-by-study basis.

Although cancer effects are associated with some studies, study-level LOAEL values should <u>not</u> be identified based on cancer effects. However, dose-related incidence information [e.g., "at doses ≥ 100 mg/kg-day, hepatocellular adenomas (7/10 male rats") and carcinomas (3/10 male rats) were observed after 2-years of exposure] for any statistically or biologically significant tumor type should be captured in the "study_comment" field in the edited/amended database deliverable.

For additional information and guidance that may be useful in the completion of Tasks 3 and 4 of this WA, please refer to Knudsen et al. (2009) and Martin et al. (2009a, 2009b) (see Part X below).

IV. ANTICIPATED DELIVERABLES

As stated above, we anticipate that the primary deliverables will be edited/amended versions of the database files ultimately submitted with this WA. All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. The use of "redline" versions of the documents shall be employed throughout the process (when applicable). All documents shall be technically edited for format and grammar before being submitted to the WAM. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Microsoft Excel, Word, and Access files).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Work Plan, Staffing Plan, and	15 days after award of Work Assignment
QAPP	
Task 3. Study Quality Evaluation	90 days after approval of the Work Plan and QAPP
(approximately 500 studies)	
Task 4. Identification of Critical Effect(s)	120 days after approval of the Work Plan and QAPP
and Establishment of Study-Level Lowest-	* * ****
Observed-Adverse-Effect Level (LOAEL)	
Values (approximately 2,500 studies)	

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM, or CO.

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and provide regular updates on progress and any issues that need to be resolved to the WAM by telephone or by email, in addition to the standard reporting requirements of the contract. Any technical directions made during informal discussions shall be issued promptly by the EPA WAM in writing (to include email).

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Scott Wesselkamper, Ph.D. 513-569-7256 (Phone) 513-487-2542 (Fax) wesselkamper.scott@epa.gov

Mailing Address:

U.S. Environmental Protection Agency National Center for Environmental Assessment 26 W. Martin Luther King Drive MS-A110 Cincinnati, OH 45268

Alternate Work Assignment Manager (Alt. WAM):

Richard Judson, Ph.D. 919-541-3085 (Phone) judson.richard@epa.gov

Mailing Address:

U.S. Environmental Protection Agency National Center for Computational Toxicology 109 T.W. Alexander Drive (MD-B-205-01) Research Triangle Park, NC 27709

X. REFERENCES

Knudsen TB, Martin MT, Kavlock RJ, Judson RS, Dix DJ, Singh AV (2009). Profiling the activity of environmental chemicals in prenatal developmental toxicity studies using the U.S. EPA's ToxRefDB. Reprod. Toxicol. 28:209–219.

Martin MT, Judson RS, Reif DM, Kavlock RJ, Dix DJ (2009a). Profiling chemicals based on chronic toxicity results from the U.S. EPA ToxRef Database. Environ. Health Perspect. 117:392–399.

Martin MT, Mendez E, Corum DG, Judson RS, Kavlock RJ, Rotroff DM, Dix DJ (2009b). Profiling the reproductive toxicity of chemicals from multigeneration studies in the toxicity reference database. Toxicol. Sci. 110:181–190.

NRC (2007). *Toxicity Testing in the 21st Century: A Vision and a Strategy*. National Research Council of the National Academies, Washington, DC.

Thomas RS, Philbert MA, Auerbach SS, Wetmore BA, Devito MJ, Cote I, Rowlands JC, Whelan MP, Hays SM, Andersen ME, Meek ME, Reiter LW, Lambert JC, Clewell HJ 3rd, Stephens ML, Zhao QJ, Wesselkamper SC, Flowers L, Carney EW, Pastoor TP, Petersen DD, Yauk CL, Nong A (2013). Incorporating new technologies into toxicity testing and risk assessment: moving from 21st century vision to a data-driven framework. Toxicol. Sci. 136:4–18.

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Title: Non-targeted analysis workshop

PERIOD OF PERFORMANCE: CO Approval – September 4, 2015

I. PURPOSE:

The purpose of this Work Assignment is to provide administrative and logistical/facilitation support services for a technical and training workshop for non-targeted laboratory analyses. The workshops will be held in in Research Triangle Park, NC in August 2015. This work assignment is consistent with the purpose and scope of Contract [EP-C14-001].

II. BACKGROUND:

Tens-of-thousands of chemicals are registered for use in the United States. The US Environmental Protection Agency is responsible for ensuring the safety of these chemicals and is authorized to regulate those that pose unreasonable risks to human health and/or the environment. Quantitative exposure data are available for only a small fraction of registered chemicals, hindering assessments of potential health risks to humans, wildlife, and ecosystems. New methods are therefore required to efficiently generate measurement data for a growing number of chemicals that remain largely unexamined. Non-targeted measurement methods, including those based on high-resolution mass spectrometry platforms, offer unique means to screen for xenobiotic chemicals in a variety of environmental and biological media. This workshop will bring together experts in non-targeted screening to discuss innovative methods and best practices for collecting, analyzing, interpreting, storing, and exchanging measurement data related to xenobiotic chemical exposures.

Participants of this workshop will discuss non-targeted analysis "success stories" and help identify:

- Best practices for using non-targeted measurement methods to identify and characterize xenobiotic chemicals in environmental and biological samples.
- Innovative and practical approaches for the analysis, interpretation, and storage of measurement data obtained via non-targeted methods.
- Challenges that may impede widespread use of non-targeted measurement techniques for exposure science.
- Collaborative opportunities to overcome challenges related to existing methodologies and/or information infrastructures.

III. STATEMENT OF WORK:

A. Objective:

The overall objective of this work assignment (WA) is to provide administrative and logistical support for a workshop about non-targeted analyses. Support will include planning for meeting and logistics, onsite meeting support and facilitation, a summary report, communication activities related to the meeting and coordinating an evaluation mechanism to solicit feedback from workshop participants. The workshop dates are August 18-19, 2015 in Research Triangle Park, NC. EPA anticipates having approximately 40-60 workshop participants. This work assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has reserved its own meeting room space for this workshop. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks):

- 1. A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
- 2. <u>Pre-meeting support:</u> Administrative and logistical support services for workshop may include:
 - A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
 - Develop a registration mechanism and coordinate registration, including maintaining a list of participants. Registration shall close one week prior to the workshop. Registration for inperson attendance may close earlier if capacity is reached.
 - Develop an abstract submission mechanism, and provide the WAM with abstracts after the submission deadline (tentatively June 19, 2015). EPA shall make final decisions about the acceptance of abstracts and develop the workshop's schedule and agenda. Contact all submitters with details about their abstract's acceptance status, presentation guidelines, and collect files for oral presentations.
 - Provide 5-10 invited participants with assistance to book travel reservations and distribute forms required for reimbursement.
 - Provide participants local information about hotels, restaurants, directions, transportation (airport, airport transportation, etc).
 - Develop a workshop website to include logistical and agenda information, registration and abstract submission mechanisms.
 - Prepare folders for distribution to attendees at registration including final agenda, meeting roster, survey for participants to fill out, name badges and other meeting materials.
 - Work with EPA's onsite facility staff to ensure meeting rooms have AV equipment including microphone, laptop computer, projectors, screen, poster boards, poster fasteners, flip charts, tape, markers etc.
 - Coordinate with EPA's onsite security staff to ensure visitors are expected and sign-in goes smoothly. Communicate with EPA visitors about the documents and procedures required for access to the facility.
 - Set up and test webinar, conference call and video conference capability for remote participation.

3. Onsite Logistical Support

- Provide staff to support the workshop onsite.
- Provide facilitation between remote attendees and in-person activities including relaying and resolving AV issues, reminding speakers to use microphones and repeat questions, and relay information (questions, feedback, information) to speakers and in-person attendees.
- Capture notes during the discussions. The notes should highlight key recommendations, decisions, and action items.
- Manage the registration table to ensure participants sign in, receive the meeting materials and handle any problems workshop participants may encounter.
- Update attendee list at the end of the workshop (remove no-shows, add walk-ins and remote participants).

• Provide on-site liaison services to work with facility staff to trouble-shoot any problem situations related to AV support, room set-up, and poster displays.

4. Post-meeting Support and Reporting

- Summarize all meeting discussions including key recommendations, decisions, and actions items in a post-meeting summary report. The report shall be delivered by electronic file within 10 days after the end of the workshop. This report should include a listing of all meeting attendees.
- Provide support to invited participants for travel expense reimbursement.
- As permitted by speakers, distribute workshop audio, video, and/or presentations.

IV. SCHEDULE OF DELIVERABLES

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date
Conduct initial contact kick-off meeting (listed above)	Within 3 days of award
Establish website for on-line registration, and abstract submission	Within 10 days of award
Provide WAM with abstracts submitted before closing deadline	Within 5 working days of abstract deadline
Contact abstract submitters with presentation information	Within 5 working days of receiving information from EPA
Submit electronic copies of registration lists and registration materials	Thirty and five working days before workshop and status updates on registration leading up to events
Submit list of visitors to EPA security personnel	As required or two working days before workshop
Submit updated list of attendees, electronic version of presentation materials, and any materials submitted by presenters prior to or following the meeting.	Ten working days following the workshop
Post-workshop final report	Ten working days following the workshop
Distribute meeting materials to participants	Ten working days following the workshop

V. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on workshop dates.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM) Elin Ulrich 919-541-3717 <u>Ulrich.Elin@epa.gov</u>

Alternate WAM Kristin Isaacs 919- 541-2785 Isaacs.Kristin@epa.gov

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Title: Non-targeted analysis workshop

PERIOD OF PERFORMANCE: CO Approval – September 4, 2015

I. PURPOSE:

The purpose of this Work Assignment is to provide administrative and logistical/facilitation support services for a technical and training workshop for non-targeted laboratory analyses. The workshops will be held in in Research Triangle Park, NC in August 2015. This work assignment is consistent with the purpose and scope of Contract [EP-C14-001].

II. BACKGROUND:

Tens-of-thousands of chemicals are registered for use in the United States. The US Environmental Protection Agency is responsible for ensuring the safety of these chemicals and is authorized to regulate those that pose unreasonable risks to human health and/or the environment. Quantitative exposure data are available for only a small fraction of registered chemicals, hindering assessments of potential health risks to humans, wildlife, and ecosystems. New methods are therefore required to efficiently generate measurement data for a growing number of chemicals that remain largely unexamined. Non-targeted measurement methods, including those based on high-resolution mass spectrometry platforms, offer unique means to screen for xenobiotic chemicals in a variety of environmental and biological media. This workshop will bring together experts in non-targeted screening to discuss innovative methods and best practices for collecting, analyzing, interpreting, storing, and exchanging measurement data related to xenobiotic chemical exposures.

Participants of this workshop will discuss non-targeted analysis "success stories" and help identify:

- Best practices for using non-targeted measurement methods to identify and characterize xenobiotic chemicals in environmental and biological samples.
- Innovative and practical approaches for the analysis, interpretation, and storage of measurement data obtained via non-targeted methods.
- Challenges that may impede widespread use of non-targeted measurement techniques for exposure science.
- Collaborative opportunities to overcome challenges related to existing methodologies and/or information infrastructures.

III. STATEMENT OF WORK:

A. Objective:

The overall objective of this work assignment (WA) is to provide administrative and logistical support for a workshop about non-targeted analyses. Support will include planning for meeting and logistics, onsite meeting support and facilitation, a summary report, communication activities related to the meeting and coordinating an evaluation mechanism to solicit feedback from workshop participants. The workshop dates are August 18-19, 2015 in Research Triangle Park, NC. EPA anticipates having approximately 40-60 workshop participants. This work assignment does not include logistical support related to securing a facility or any meeting rooms. EPA has reserved its own meeting room space for this workshop. Administrative and logistical support shall consist of the following tasks:

B. Specific Requirements (Tasks):

- 1. A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
- 2. <u>Pre-meeting support:</u> Administrative and logistical support services for workshop may include:
 - A kick-off meeting shall be held (in person and/or by phone) between the Contractor and WAM to clarify or address questions. The contractor shall maintain communication with the EPA WA Manager (WAM) through weekly phone calls or email updates.
 - Develop a registration mechanism and coordinate registration, including maintaining a list of participants. Registration shall close one week prior to the workshop. Registration for inperson attendance may close earlier if capacity is reached.
 - Develop an abstract submission mechanism, and provide the WAM with abstracts after the
 submission deadline (tentatively June 19, 2015). EPA shall make final decisions about the
 acceptance of abstracts and develop the workshop's schedule and agenda. Provide Contact-all
 submitters with details about their abstract's acceptance status, presentation guidelines
 through the website, and collect files for oral presentations.
 - Provide 5-10 invited participants with assistance to book travel reservations and distribute forms required for reimbursement.
 - Provide participants local information about hotels, restaurants, directions, transportation (airport, airport transportation, etc).
 - Develop a workshop website to include logistical and agenda information, registration and abstract submission mechanisms.
 - Prepare folders for distribution to attendees at registration including final agenda, meeting roster, survey for participants to fill out, name badges and other meeting materials.
 - Work with EPA's onsite facility staff to ensure meeting rooms have AV equipment including microphone, laptop computer, projectors, screen, poster boards, poster fasteners, flip charts, tape, markers etc.
 - Coordinate with EPA's onsite security staff to ensure visitors are expected and sign-in goes smoothly. Communicate with EPA visitors about the documents and procedures required for access to the facility.
 - Set up and test webinar, conference call and video conference capability for remote participation.

3. Onsite Logistical Support

- Provide staff to support the workshop onsite.
- Provide facilitation between remote attendees and in-person activities including relaying and resolving AV issues, reminding speakers to use microphones and repeat questions, and relay information (questions, feedback, information) to speakers and in-person attendees.
- Capture notes during the discussions. The notes should highlight key recommendations, decisions, and action items.
- Manage the registration table to ensure participants sign in, receive the <u>Provide</u> meeting materials for the registration table (staffed by EPA) and handle any problems workshop participants may encounter.

- Update attendee list at the end of the workshop (remove no-shows, add walk-ins and remote participants).
- Provide on-site liaison services to work with facility staff to trouble-shoot any problem situations related to AV support, room set-up, and poster displays.

4. Post-meeting Support and Reporting

- Summarize all meeting discussions including key recommendations, decisions, and actions items in a post-meeting summary report. The report shall be delivered by electronic file within 10 days after the end of the workshop. This report should include a listing of all meeting attendees.
- Provide support to invited participants for travel expense reimbursement.
- As permitted by speakers, distribute workshop audio, video, and/or presentations.

IV. SCHEDULE OF DELIVERABLES

The following table provides a complete list of required work assignment tasks that are to be completed as part of this contract.

Work Assignment Task	Required Completion Date
Conduct initial contact kick-off meeting (listed above)	Within 3 days of award
Establish website for on-line registration, and abstract submission	Within 10 days of award
Provide WAM with abstracts submitted before closing deadline	Within 5 working days of abstract deadline
Contact abstract submitters with presentation information	Within 5 working days of receiving information from EPA
Submit electronic copies of registration lists and registration materials	Thirty and five working days before workshop and status updates on registration leading up to events
Submit list of visitors to EPA security personnel	As required or two working days before workshop
Submit updated list of attendees, electronic version of presentation materials, and any materials submitted by presenters prior to or following the meeting.	Ten working days following the workshop
Post-workshop final report	Ten working days following the workshop
Distribute meeting materials to participants	Ten working days following the workshop

V. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy

- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

VI. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

Travel: Any non-local travel directly chargeable to this work assignment shall be submitted and approved by the Project Officer prior to the travel (see contract clause Local LC-31-08, Approval of Contractor Travel). It is expected that the Contractor will be requested to participate in a 2-day workshop in the Research Triangle (NC) area on workshop dates.

EPA GREEN MEETING REQUIREMENTS: When soliciting quotes or offers for meeting and conference services on behalf of the EPA, the Contractor shall follow the contract EPAAR clause 1552.223-71, EPA Green Meetings and conferences. More information about EPA's Green Meetings initiative may be found on the internet at http://www.epa.gov/oppt/greenmeetings/.

VII. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM) Elin Ulrich 919-541-3717 Ulrich.Elin@epa.gov

Alternate WAM Kristin Isaacs 919- 541-2785 Isaacs.Kristin@epa.gov

	United States Environmental Protection Agency			Work Assignment Number				
EDA		Washington, DC 20460				1-63		
EPA	Work As	ssignment			Other	X Amendm	nent Number:	
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Cumulative Approved: Cost/Fee: \$34,066.00			LOE	LOE: 300				
Work Assignment Manager Name Elin Ulrich			Bra	Branch/Mail Code:				
			Pho	Phone Number 919-541-3717				
(Signature) (Date)			FAX	FAX Number:				
Project Officer Name Melissa Revely-Wilson			Bra	Branch/Mail Code:				
			Pho	Phone Number: 703-347-8523				
(Signature) (Date)			FA>	FAX Number: 703-347-8696				
Other Agency Official Name				Bra	Branch/Mail Code:			
			Pho	Phone Number:				
(Signature) (Date)				FAX Number:				
Contracting Official Name Adam Meier			-	Branch/Mail Code:				
				Phone Number: 513-487-2852				
(Signature)		(Date)	FA>	Number: 513-4	8/-2107		

	United States Enviro	United States Environmental Protection Agency			Work Assignment Number			
EPA		Washington, DC 20460				1-64		
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Contract Number	Contract Period 1	l1/01/2013 To	10/31/2	2015	Title of Work Assign	ment/SF Site Nan	ne	
EP-C-14-001	Base	Option Period Nur			Soil and Du:	st Ingesti	on Study	
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Purpose: X Work Assignment		Work Assignment C	Close-Out		Period of Performan	ce		
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Work Assignment Manager Name Linda Phillips			Bran	Branch/Mail Code:				
			Phor	Phone Number 703-347-0366				
(Signature) (Date)			FAX	FAX Number:				
Project Officer Name Melissa Revely-Wilson			Bran	Branch/Mail Code:				
			Phor	Phone Number: 703-347-8523				
(Signature) (Date)			FAX	FAX Number: 703-347-8696				
Other Agency Official Name			Bran	Branch/Mail Code:				
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(Signature) (Date)				FAX Number:				
Contracting Official Name Adam Med	er				ch/Mail Code:			
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(6)				_ I \	Ni	87-2107		

PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 1-64

TITLE: Statistical Support for Development of a Feasibility Assessment for a Soil and Dust Ingestion Study

Specify Section & Paragraph SOW: III.C.

PERIOD of PERFORMANCE: CO approval through 10/31/2015.

I. PURPOSE.

The purpose of this work assignment is for the US Environmental Protection Agency's (EPA), Office of Research and Development (ORD), National Center for Environmental Assessment (NCEA) to obtain statistical support to evaluate the feasibility of conducting a study to estimate soil and dust ingestion rates among various age groups of children (0-<1 month; 1-<3 months; 3-<6 months; 6-<12 months; 1-<2 years; 2-<3 years; 3-<6 years; 6-<11 years; 11-<16 years; 16-<21 years) and adults in the US.

II. BACKGROUND AND OBJECTIVES.

Soil and dust ingestion are important pathways of exposure to certain environmental contaminants, especially for children. Assessing exposure via these pathways requires information on soil and dust ingestion rates. There are three basic approaches for estimating soil/dust ingestion rates, as reported in the scientific literature: tracer studies, activity pattern studies, and biokinetic modeling comparison studies. Tracer studies estimate soil/dust ingestion based on measurements of tracer elements present in soil/dust from children's residences and/or play areas, and the children's feces. Activity pattern studies combine information on hand-to-mouth and object-tomouth activities with assumptions about transfer of soil and dust to hands and from hands to mouth and other exposure factors (e.g., frequency of hand washing) to derive soil and dust ingestion estimates. Micro-activity information is usually obtained using observational techniques (e.g., videography) or from survey responses. Biokinetic modeling comparison studies compare direct measurements of a biomarker (e.g., blood or urine levels of a toxicant) with predictions from a biokinetic model (e.g., IEUBK). The comparison of the model predicted blood lead levels with actual blood lead levels can be used to confirm the model's input assumptions on soil and dust intake rates. The available soil and dust ingestion data based on these three study types are reviewed in detail in EPA's Exposure Factors Handbook: 2011 Edition¹, but the data are limited and ingestion rates are not available for all age ranges (0-<1 month; 1-<3 months; 3-<6 months; 6-<12 months; 1-<2 years; 2-<3 years; 3-<6 years; 6-<11 years; 11-<16 years; 16-<21 years) of children. Therefore, ORD is considering the feasibility of collecting additional soil and dust ingestion data to fill critical data gaps using the tracer and/or activity pattern approaches. As such, ORD is conducting a feasibility study for internal EPA use that will include a comprehensive review and evaluation of the design elements associated with these approaches, including, statistical design (sample sizes and locations), sample collection methods, analytical methods, cost, consent and approval, and other implementation factors. The purpose of this work assignment is to obtain support for the statistical design of such a study; specifically, estimating sample sizes required to ensure a representative sample for various age ranges of the US population, considering various demographic factors (see Attachment 1).

¹ EPA/600/R-09/052F; and Moya, J. and Phillips, L. (2014) A review of soil ingestion studies for children. J Expos Sci Env Epidem, 24: 545-554.

III. STATEMENT OF WORK.

The contractor shall be responsible for completion of five tasks. A summary of each task is provided below, including the time frame during which the task shall be completed.

Task 1. The contractor shall establish initial communication, submit a work plan, and arrange for routine updates for the EPA Contracting Officer's Representative (COR).

The contractor shall schedule an initial conference call with the EPA COR within 1 week after the receipt of the work assignment to discuss any questions that ICF may have before submitting the work plan.

Deliverable 1: The contractor shall arrange a conference call with the COR, within 1 week after the receipt of the work assignment.

Task 2. The contractor shall arrange a conference call to discuss the technical basis of this task with EPA

EPA ORD has established a team of scientists to work on development of a feasibility assessment of the soil and dust ingestion study. The contractor shall organize a meeting between these EPA ORD scientists and the ICF statistician(s) working on this work assignment to discuss the scope of the project. The contractor(s) shall familiarize themselves with the soil ingestion data in the *Exposure Factors Handbook* and Attachment 1 of this Statement of Work prior to the meeting. **Within 3 weeks after Work Plan approval,** the contractor shall arrange for a conference call with the EPA-COR and the EPA ORD scientists working on the feasibility assessment to discuss the scope of this work assignment. This call will inform selection of the three options in Task 3.

Deliverable 2: The contractor shall arrange a conference call within 3 weeks after Work Plan approval.

Task 3. The contractor shall propose options that represent three levels of statistical power for estimating the sample sizes.

The contractor shall propose three options for estimating sample sizes. These three options shall represent different levels of statistical power (e.g., high, medium, and low of confidence) to ensure adequate sample size and representativeness (e.g., age, gender, geographical, seasonal, socioeconomic factors, etc.), to allow for development of distributions and confidence intervals for key distributional parameters, and to identify statistical differences between population groups (e.g., age, gender). The contractor shall submit the draft proposal along with complete descriptions of the three options and their potential impacts on the potential study within 2 weeks after completing Task 2. The contractor shall submit final options and text within 2 weeks of receiving comments on the draft options from the COR.

Deliverable 3a: The contractor shall submit draft options within 2 weeks after completing Task 2.

Deliverable 3b: The contractor shall submit final options within 2 weeks of receiving comments on the

draft options from the COR.

Task 4. The contractor shall estimate the sample sizes required based on the three statistical options.

EPA has outlined potential demographic categories for consideration in determining the number of observations (Ns) needed to ensure that a statistically representative sample is collected (see Attachment 1). These

demographic categories may be prioritized during development of the study design based on funding and other factors. The contractor shall estimate the overall sample size (Total N), and Ns within the various categories, based on the 3 options developed in Task 3. The contractor shall provide the COR 3 tables, based on the results for the 3 options, within 4 weeks of receiving the COR's concurrence on the options developed in Task 3. Within 2 weeks after completing any necessary revisions, based on the COR's comments/questions, the contractor shall develop final tables and submit them to the COR.

Deliverable 4a: The contractor shall submit to the COR draft tables of the estimated study Ns, based on

the 3 statistical options within 4 weeks after receiving EPA concurrence on Task 3.

Deliverable 4b: The contractor shall submit final tables within 2 weeks of receiving

comments/questions from the COR.

Task 5. The contractor shall provide a complete description of the methods and results of the estimated samples size analysis.

The contractor shall provide a complete description of the methods and results of the estimated sample size analyses based on the three selected options. The text shall be of suitable detail and quality for incorporation into a feasibility report being developed by EPA. The contractor shall provide the COR with the draft text within 2 weeks of completing Task 4. The contractor shall provide the COR with final text within 2 weeks of receiving comments from the COR.

Deliverable 5a: The contractor shall provide the COR with draft text within 2 weeks of completing Task

4.

Deliverable 5b: The contractor shall provide the COR with final text within 2 weeks of receiving COR

comments on the draft text.

The contractor shall furnish electronic copies of (or internet links to) any references or other materials obtained in the preparation of the deliverables for this work assignment.

.IV. TIME TABLE.

Task	Deliverable	Time frame
1a	Establish initial communication	Within 1 week after receipt of work assignment
2	Hold conference call with EPA staff and contractor statisticians	Within 3 weeks of Work Plan approval
3a	Submit draft options	Within 2 weeks of completing Task 2
3b	Submit final options	Within 2 weeks of receiving comments from COR
4a	Submit draft tables of study Ns	Within 4 weeks of COR concurrence on Task 3
4b	Submit final tables of study Ns	Within 2 weeks of COR comments
5a	Submit draft text	Within 2 weeks of completing Task 4
5b	Submit final text	Within 2 weeks of receiving comments from COR

- 1. The contractor shall be responsible for obtaining a conflict of interest certification for any subcontractor services.
- 2. All deliverables shall be in conformance with the requirements of the work assignment before such deliverables are approved as final. Electronic copy of all deliverable shall be sent to the EPA Project Officer (PO).
- 3. The contractor shall comply with other applicable requirements for final work assignment reports as stipulated in the Contractual Agreement.
- 4. The contractor shall prepare all deliverables in accordance with the Quality Management Plan for the contract.

V. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS TASK ORDER.

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

If the contractor receives any instructions from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately notify the COR. The contractor shall also ensure that work under this Work Assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that no conflicts exist at the time the proposal is submitted to the EPA.

VII. EPA CONTACT INFORMATION.

Copies of all correspondence pertaining to the performance of this work assignment shall be sent electronically to the COR.

Work Assignment Manager

Linda Phillips

US EPA (8623P)

National Center for Environmental Assessment

Office of Research and Development

U.S. Environmental Protection Agency

1200 Pennsylvania Ave. NW

Washington, DC 20460

Telephone #: (703) 347-0366

FAX #: (703) 347-8690

Email: phillips.linda@epa.gov

Alternate WAM

Jacqueline Moya

US EPA (8623P)

National Center for Environmental Assessment

Office of Research and Development

U.S. Environmental Protection Agency

1200 Pennsylvania Ave. NW

Washington, DC 20460

Telephone #: (703) 347-8539

FAX #: (703) 347-8694

Email: moya.jacqueline@epa.gov

Attachment 1

DRAFT

SOIL/DUST INGESTION STUDY DESIGN

Potential demographic categories for consideration to determine number of observations (Ns) needed to ensure that a statistically representative sample is collected

Soil/Dust Ingestion Study – Target Population (Ns) ^a												
Study Elements	Birth to <1 month	1 to <3 months	3 to <6 months	6 to <12 months	1 to <2 years	2 to < 3 years	3 to <6 years	6 to <11 years	11 to <16 years	16 to < 21 Years	Adult 21+ years	
Total N												
Gender												
Males												
Females												
Race/ethnicity												
White												
Black												
Hispanic												
Asian												
Native American												
Other												
Geographic Areas ^b												
Northeast												
Midwest												
South												
West												
Urbanicity												
Urban												
Suburban												
Rural												
Soil type within residential location												
Loamy												
Sandy												
Clay												
??												
Season												
Fall/Winter												
Spring/Summer					_							
Weather conditions (during study period)												
Sunny/Fair												
Rain/Snow												

Soil/Dust Ingestion S	tudy –	Tar	get F	opul	atio	n (Ns	s) ^a				
Study Elements	Birth to <1 month	1 to <3 months	3 to <6 months	6 to <12 months	1 to <2 years	2 to < 3 years	3 to <6 years	6 to <11 years	11 to <16 years	16 to < 21 Years	Adult 21+ years
Weekday (M-F)											
Weekend (S/S)											
Socioeconomic status (household											
income)											
<\$10,000											
\$10,000 to <\$25,000											
\$25,000 to<\$50,000											
\$50,000 to <\$100,000											
\$100,000 to <\$200,000											
>\$200,000											
WIC status											
Yes											
No											
Housing type											
Multi-family											
Single Family											
House age											
<10 year 10 to <25 years											
>25 years											
Vacuuming Vacuuming											
<1x/month											
1x/month to <1x/week											
>1x/week											
Behavioral Habits	X	X	Х	х							
Removes shoes in house											
Wears shoes in house											
Education Level of head of household											
<high school<="" td=""><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></high>											
High School Graduate											
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College Graduate											
Post Graduate											
Employment status of head of household											
Part time											
Full time											
Not employed											
Retired						,					

Soil/Dust Ingestion St	udy –	Tar	get P	opul	latio	n (Ns	s) ^a				
Study Elements	Birth to <1 month	1 to <3 months	3 to <6 months	6 to <12 months	1 to <2 years	2 to < 3 years	3 to <6 years	6 to <11 years	11 to <16 years	16 to < 21 Years	Adult 21+ years
Attends Daycare (young children only)								X	X	X	х
Yes											
No State (11) C 1 15 14											
Pregnancy Status (adult females, 15-44	X	X	X	X	X	X	X	X	X	X	
years)											
Not pregnant											
Pregnant											
Control population (e.g., hospitalized)											
Oversample potential pica population											
(based on questionnaire data)											
Subsample to obtain longitudinal data											
(i.e., over longer period of time)											

This is not a nested design; each category is intended to be separate; e.g., geographic regions are not further subdivided by race/ethnicity.

Midwest = Locations in Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and/or Wisconsin

South = Locations in Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and/or West Virginia

West = Locations in Arizona, California, Colorado, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and/or Wyoming

N = Number of observations

Northeast = Locations in Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and/or Vermont

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Work Assignment Manager Name Linda F	hillips			Brar	nch/Mail Code:			
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Project Officer Name Melissa Revely	<i>y-</i> Wilson				nch/Mail Code:			
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Other Agency Official Name				Brar	nch/Mail Code:			
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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 1-64 AMENDMENT 1

TITLE: Statistical Support for Development of a Feasibility Assessment for a Soil and Dust Ingestion Study

This Amendment 1 adds the following Task to work assignment 1-64 of this contract:

Task 6. The Contractor shall estimate the types and number of samples needed from the sample population.

Under this task the contractor shall assist EPA with the feasibility assessment for a soil/dust ingestion study by estimating the types and numbers of samples that will need to be collected and analyzed, based on the number of study participants estimated for the three design options developed under Task 4 of this work assignment. The contractor shall schedule an initial conference call **within 1 week** after the receipt of this amendment to discuss the development of these estimates with EPA.

It is anticipated that the soil/dust ingestion study will use both tracer and activity pattern methodologies. The contractor shall develop a draft list of the types (e.g., fecal, urine, soil, food, videography, hand presses for adherence), and number of samples needed for each study participant (e.g., based on sample collection frequency, statistical power, differences expected, sieving of soil samples) for each of these approaches. The contractor shall also identify the number of analyses needed (e.g., no more than 5 tracer chemicals; creatinine in urine and/or specific gravity; soil type) for each type of sample. The contractor shall clearly outline all assumptions (e.g., sampling frequency; study duration; longitudinal sample collection for a subset of participants; compositing of samples for analysis; statistical power; differences expected) made in developing the list and estimating the total number of samples and analyses. The draft list shall be submitted to the EPA WAM within 2 weeks after the initial conference call. A final list shall be submitted 2 weeks after receiving comments from the EPA WAM.

Deliverable 6a: The contractor shall arrange a conference call with the WAM, within 1 week of

the receipt of this amendment.

Deliverable 6b: The contractor shall provide a draft list of sample and analysis types and

numbers within 2 weeks after the initial conference call.

Deliverable 6c: The contractor shall provide a final list within 2 weeks after receiving

comments from the EPA WAM.

Task	Deliverable	Time frame
6a	Establish communication via conference call	Within 1 week after receipt of Amendment 1
6b	Submit a draft list of sample and analyses types and numbers	Within 2 weeks after initial conference call
6c	Submit a final list of sample and analyses types and numbers	Within 2 weeks of receiving EPA comments

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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 1-65

TITLE: Peer Consultation Webinar Workshop on Model Averaging Methods for Dose-Response Analysis in Support of USEPA Health Assessments

SOW Section & Paragraph: A. Assessment Issues and Documents; E. Risk Assessment Support - Meetings

PERIOD of PERFORMANCE: CO approval through 10/31/2015

I. Purpose

The purpose of this work assignment (WA) is to identify, recruit, and manage qualified scientists to participate in a workshop via web conference, to take place no later than October 2015, with the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), in the Office of Research and Development (ORD). This workshop aims to assist EPA in identifying a preferred model averaging method(s) for dose-response analysis through an examination of candidate model averaging methods that EPA has researched for continuous response measures, and the potential for extension of any preferred method(s) identified to dichotomous response measures. This work assignment is consistent with the purpose and scope of Contract EP-C-14-001.

II. Background

The benchmark dose (BMD) method is a key component of chemical risk assessments performed by EPA, other U.S Federal and State Agencies, and multiple international organizations (USEPA, 2012; RIVM, 2009; EFSA, 2005 and 2009; JECFA, 2006). The BMD method is used to establish guideline values such as USEPA reference doses and cancer slope factors (USEPA, 2012) for chemicals expected to have ecological or human health effects. Existing BMD methods involve the selection of a single dose-response model from among a suite of models with little biological basis, based largely on a comparison of model fits to the data. As such, it has been criticized for not adequately accounting for model uncertainty and biological considerations. Model averaging is a recognized and well published scientific approach for addressing model uncertainty, with the potential for incorporating biological considerations. Bayesian methods can be applied to allow prior information, including biological considerations, to influence model averaging results. Given these potential benefits, model averaging was identified as one of the USEPA's top FY 2012-2014 priorities for strengthening dose-response modeling under EPA's Human Health Risk Assessment program for "Advancing Dose-Response Analysis and Characterization" and several model averaging approaches, primarily with focusing on continuous response measures, have been investigated and tested by the USEPA over the past two years.

EPA NCEA plans to hold a half-day webinar workshops in 2015 to obtain peer input on model averaging methods for dose-response analysis. To facilitate the workshop, EPA NCEA has prepared a report describing methods that are consistent with published recommendations, software that illustrates how those existing methods could be implemented and questions that EPA would like the panel to address. Workshop panelists shall be asked to assess these materials and provide input that will help EPA determine the value and optimal model averaging methods for dose-response analysis of continuous response measures, as well as the potential for extension of preferred methods to dichotomous response measures.

III. Statement of Work

The overall objective of this WA is to identify, recruit, and manage expert scientists to participate in a workshop to be conducted via web conference on the subject of model averaging methods for dose-response analysis. It is expected that this workshop shall have approximately 6-10 panel participants, including invited external experts and EPA staff members. Contractor support shall consist of the following tasks:

Task 1: Establish communication

Within 3 days of award of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall maintain communication with the WAM through bi-weekly phone calls or email updates.

Task 2: Work Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, level of effort, and a staffing plan that shows assigned personnel by task and the qualifications of the proposed personnel.

The Contractor shall not perform any work under this WA until the Work Plan is reviewed and approved.

Task 3: Initial planning meeting with EPA

The Contractor shall schedule an initial planning meeting via conference call (not to exceed 2 hours) within 7 days of establishing communication in Task 1 with the WAM and other EPA scientists working on the development of EPA model averaging methods. The purpose of this planning meeting will be to:

- Discuss and clarify requirements of the tasks in this WA
 - Discuss pre-workshop logistics, including:
 - Possible panel participants
 - o Public announcements
 - Distribution of pre-workshop materials (report, software and charge questions)
 - o Collection and collation of pre-workshop comments from panel participants
- Discuss workshop logistics, including:
 - Workshop date
 - Preparation and distribution of workshop materials (agenda, pre-workshop comments from panel participants, workshop goals, list of participants, presentations submitted by panelists and registered speakers, web conference logistics)
- Review the requirements and timeline of this WA

<u>Task 4: Selection of expert workshop panel participants</u>

a. *Identify candidate panel participants.* Upon request EPA will provide the Contractor with a list of qualified candidate panel participants. From this list and/or independent investigation, the Contractor shall identify a pool of 3-5 EPA and 3-5 non-EPA scientists with representation from the following scientific areas:

- Chemical health assessment, with a focus on USEPA practice/methods
- Benchmark dose modeling, with a focus on application to animal toxicology data
- Dose-response model averaging
- Bayesian statistics, with a focus on their application to the areas listed above
- b. Panel Participant invitations and agreements. The Contractor shall draft an initial email to selected candidate panel participants summarizing the workshop's objectives, estimated levels of effort and time commitment, and compensation terms (where appropriate, for non-EPA panel participants). The Contractor shall indicate to the selected candidate panel participants that their presence will be required throughout the duration of the workshop, and they will be required to participate in discussions amongst themselves evaluating the scientific data and addressing the outlined objectives. These objectives will be supplied to the experts in the form of charge questions. The workshop proceedings will be captured in a summary document prepared by the Contractor following the workshop.

Once the draft email text has been approved by the WAM, the Contractor shall direct the candidate panel participants to reply with their availability and willingness to engage, CV or similar summary of professional experience, and current contact information, including their institutional affiliation, mailing address, telephone numbers, and other email addresses. If a consensus on a date for the workshop cannot be reached by a quorum of invited experts, the Contractor shall work in consultation with the WAM to identify alternative candidate panel participants for the workshop in order to optimize the number of panel participants.

c. Response tracking and purchase orders. The Contractor shall develop a database (in Word or an Excel spreadsheet) to compile and track responses to the invitations, CVs, and contact information for invited panel participants. The Contractor shall send weekly updates of the database to the WAM for review.

The contractor shall ensure that all participants agree to material terms (tasks, expectations, availability, compensation, COI certification). The Contractor shall follow up with non-responders by email or telephone to determine their interest and availability.

Task 5: Public participation and registration for workshop

Members of the public and other interested parties may wish to attend the workshop. These attendees will have the option of presenting a short (≤15 minutes) presentation to the panel before discussions begin. To this end, the Contractor shall maintain a workshop registration webpage to provide information on the workshop and assist in public registration by collecting and managing information from the registrants, including the name, title, all affiliations, who the individual is representing and whether the individual was financially compensated for their presentation, and contact information (i.e. email and mailing addresses, phone numbers) for each participant. The website should indicate that there will be an opportunity for public comment at the start of the workshop. Registrants must identify whether they would like to attend as an "observer" or a "speaker," and, if requesting to speak, provide a slide presentation (in PowerPoint or as a PDF) to the Contractor by the end of the registration period. In general, these attendee presentations should be no more than 15 minutes. The registration process will be announced by EPA.

EPA will designate the starting and closing dates of the registration period and the date for the web conference. The registration period begins on the day the web conference is announced by EPA to the

public. The registration period ends one week before the date of the web conference. The list of registered attendees shall be provided to EPA within three working days of the close of the web conference registration. The Contractor shall generate an agenda for the web conference based on the number of registered speakers. The order of speaker presentations shall follow the order of registration.

Task 6: Distribution of pre-workshop materials

Following technical direction from the WAM, the Contractor will collect pre-workshop materials (to be supplied by EPA) and distribute them along with a letter of invitation to all invited experts within five days of EPA approval via email and no less than 6 weeks prior to the workshop date. The invitation will include instructions to the panel participants, including a deadline for returning written comments that is 10-14 days prior to the workshop date. The Contractor will copy the WAM on all pre-workshop material emails. The Contractor will also mail hard copies of all of the pre-workshop materials along with a letter of invitation to each participant, if requested. Each pre-workshop package will include the following materials:

- A Model averaging report describing model averaging methods and preliminary test results
- Prototype software for implementing methods described in the model averaging report
- Charge questions to panel participants

Task 7: Collection and collation of pre-workshop comments from panel participants

The Contractor will collect and collate comments from the panel participants, and prepare a single draft report organized by charge questions in a format agreed upon at the initial planning meeting (Task 3). Within 10-14 days of the workshop date, the contractor shall e-mail a draft of the comment report to the EPA WAM and alternate WAM and schedule a teleconference meeting to discuss the draft report with EPA. The contractor shall then revise the draft report based on comments received from EPA at the teleconference meeting.

Task 8: Preparation and distribution of workshop materials

Following technical direction from the WAM or alternate WAM, the Contractor will prepare workshop materials, obtain EPA approval of them, and distribute them to all invited experts within five days of EPA approval via email, and no less than 1 week prior to the scheduled workshop date. The Contractor will copy the WAM and alternate WAM on all workshop material emails. The Contractor will also mail hard copies of all of the workshop materials along with a letter of invitation to each participant, if requested. Workshop materials will also be made available to the public online in a web format agreed upon at the initial planning meeting (Task 3). Each workshop package will include the following materials:

- Report containing collated comment from panel participants
- Statement of workshop goals
- Draft agenda
- List of workshop attendees (expert panel members and any registered public speakers)
- Presentations submitted by panel participants and registered public speakers
- General information sheet on web conference logistics

Task 9: Conduct the workshop

The EPA web conference should last approximately one-half day, no later than October, 2015 (not specific). The Contractor shall handle the logistics of holding the web conference, which will be based at the U.S. EPA NCEA office in RTP, NC. EPA currently utilizes Adobe Connect for webinars, but a web conference of this type will require constant monitoring to ensure public and panel participants do not lose audio or video connections.

Task 10: Final workshop summary report and workshop close-out

Development of final workshop summary report. Following the workshop, the Contractor shall generate a final workshop summary report to be compiled from notes taken during the meeting, audio recordings, information from written pre-workshop comments, presentations at the workshop by the expert panel, and any other materials generated or used by the expert panel. A draft of this summary report shall be submitted to EPA along with the reproduction of any handwritten materials developed during the meeting within two weeks of the meeting. The presentations made by the registered public speakers along with notes from these presentations shall also be generated and attached to the workshop summary report as an appendix.

EPA will provide comments on the draft summary report to the Contractor; the final summary report draft shall be submitted to EPA two weeks after these comments have been received by the Contractor. The Contractor shall email the electronic file of the final summary report to the invited expert panel participants.

IV. Schedule of Deliverables

	<u>Deliverables</u>		<u>Due Dates</u>
1.	Establish communication (Г1)	Within 3 days of award
2.	Workplan (T2)	Within 15 days of award	
3.	Initial planning meeting wi	th EPA (T3)	Within 21 days of award
4.	Identify and contact candid workshop participation (Te		Within 30 days of award
5.	Identify date and time of w	orkshop (T4)	Within 30 days of award
6.	Set up online registration f and/or speakers (T5)	or public observers	Within 30 days of award
7.	Distribute pre-workshop n	naterials (T6)	Within 5 days of receipt of materials and approval from WAM and no less than 6 weeks prior to workshop date
8.	Collect pre-workshop com	ments from panelists (T7)	10-14 days prior to workshop
9.	Distribute workshop mater	rials (T8)	Within 5 days of EPA approval, and no less than 1 week prior to workshop date

10. Conduct workshop (T9)

No later than Oct 2015 (not specific)

11. Draft a workshop summary report Within 2 weeks following workshop

12. Submit final workshop summary report after Within 2 weeks following receipt of

incorporating comments from EPA EPA comments

V. Management Controls

All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

VI. Notice Regarding Guidance Provided Under this Project

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

(1) Formulation of Agency policy

- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO or WAM.

The contractor shall also ensure that work under this work assignment does not contain any apparent or real personal or organizational conflict of interest. The contractor shall certify that none exist at the time the proposal is submitted to EPA.

VII. Special Conditions and Assumptions

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone or email for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

VIII. EPA Contact Information

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

IX. Work Assignment Manager (WAM)

Jeffrey S. Gift, Ph.D.

Telephone: 919-541-4828

Fax: 919-541-0245 e-mail: gift.jeff@epa.gov

Mailing Address:

U.S. Environmental Protection Agency Office of Research and Development National Center for Environmental Assessment (MC B-243-01) Research Triangle Park, NC 27711

ALTERNATE WORK ASSIGNMENT MANAGER:

Allen Davis

Telephone: 919-541-3789

Fax: 919-541-0245

e-mail: davis.allen@epa.gov

Mailing Address:

U.S. Environmental Protection Agency Office of Research and Development National Center for Environmental Assessment (MC B-243-01) Research Triangle Park, NC 27711

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PERFORMANCE WORK STATEMENT WA 1-66

TITLE: Convening and Facilitation Support for EPA's Children's Health Protection Advisory Committee

Specify Section & Paragraph SOW: (1) Dissemination of Information, (2) Preparation of Technical Publications, (3) Preparation of Electronic Products, and (4) Logistical and Technical Support for the Conduct of Meetings. (5) OTHER REQUIREMENTS

PERIOD OF PERFORMANCE: Award to October 31, 2016

I. Background:

The Office of Children's Health Protection (OCHP) in the Office of the Administrator was formed in February 1997. The plans for this office include the convening of the Children's Health Protection Advisory Committee (CHPAC). CHPAC supports and furthers EPA's commitment to child-protective environmental standards; research policies on children's unique susceptibility and exposure to pollutants; community involvement and education on children's environmental health; and to economic, legal and public health issues as they apply to children. The CHPAC provides advice to EPA (the Agency) on issues of children's environmental health protection in the areas of science and research, regulatory issues, communications and outreach.

OCHP has established this balanced, broad-based Federal Advisory Committee comprised of stakeholders from many points of view. The CHPAC is chartered every 2 years. The first meeting was held in December 1997 and the charter has been renewed until September 30, 2017.

The CHPAC operates on a consensus basis and does most work by conference calls. Plenary meetings are usually in the Washington, DC area and take place about 3 times per year for two to three days. Work group meetings are often held in conjunction with the plenary sessions. Some work group meetings may be held in other locations as needed.

II. Scope/Objective Statement

The purpose of this work assignment is to describe services and support to EPA's CHPAC. The CHPAC has up to 30 plenary members and involves ad hoc work groups. OCHP will establish ad hoc task groups from time-to-time throughout the implementation of this work assignment.

III. Performance Objective 1: Work Plan and Budget

Task 1: Establish communication

Within 3 days of award of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WA-COR and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks. The Contractor shall maintain communication with the WA-COR through biweekly phone calls or email updates. The Contractor shall prepare a work plan and budget. The work plan shall outline, describe, and include the technical approach, resources, time line, and due dates for deliverables.

Overall management effort of the work assignment, including planning meetings, conference calls, monthly reports and effort associated with closeout after physical completion shall be addressed explicitly under this task.

Deliverables:

The Contractor shall prepare a conference call and Cost Estimate, including the proposed level of effort, cost plus fixed fee, and a schedule of tasks within 20 calendar days of the date of receipt of this SOW, and submit it to the Work Assignment Contracting Officer Representative (WA COR), the Project Officer, and the Contracting Officer for their respective approvals.

IV. Performance Objective 2: Preliminary Work

- 1. The dispute resolution professional(s) shall meet with the Work Assignment Contracting Officer Representative (WA-COR) and the CHPAC Designated Federal Officer (DFO) as needed to discuss substantive and procedural issues and define potentially involved interests and parties.
- 2. The Contractor shall be responsible for oversight of deliverables and shall be responsible for transmission of monthly reports and invoices as required by the contract.

V. <u>Performance Objective 3</u>: Convening Activities and Continuing Organizational Issues

- 1. In consultation with the WA-COR and DFO, the contractor shall identify and contact affected interest groups (for task groups and any plenary members that may need to be replaced) and potential parties to discuss the goals and purpose of the CHPAC and the technical or substantive issues of the CHPAC for plenary or work group sessions.
- 2. The contractor, in consultation with the WA-COR and DFO, shall contact potential parties to obtain commitments to participate in the CHPAC plenary and work groups.

Deliverable:

- 1. Reports weekly after declaration of need.
- 2. Written schedule to track milestones periodically as needed or if requested by DFO.

VI. Performance Objective 4: Facilitation

- 1. The contractor, in consultation with the WA-COR and CHPAC Designated Federal Officer (DFO), shall understand, implement and revise if necessary the CHPAC operating principles and ground rules. At any time during the life of the CHPAC, the contractor, in consultation with the WA-COR and CHPAC Designated Federal Officer (DFO), shall assist the group in further developing and refining the ground rules or operating principles of all committee and shall distribute these rules to the committee members.
- 2. The contractor shall provide a final agenda to the WA-COR and the DFO for each CHPAC plenary meeting and work group meetings. The contractor shall distribute the final agenda to the WA-COR, DFO, committee members, other participants, and interested parties. The agenda shall reflect superior professional expertise in meeting design.
- 3. The contractor shall ensure accuracy of agenda and post the plenary agenda to the CHPAC and OCHP web pages 2 to 3 weeks prior to the plenary. The contractor shall ensure that upcoming CHPAC meeting

dates and locations are posted to the OCHP and CHPAC web page at least 2 months prior to the next plenary meeting. In consultation with the DFO, the contractor shall work to ensure accuracy and completeness of the CHPAC web pages and shall work to ensure continued improvement and accessibility of information.

- 4. The contractor, in consultation with the WA-COR and CHPAC Designated Federal Officer (DFO), shall communicate in person, by phone or in writing with committee members and other participants between meetings to ensure that CHPAC issues and concerns have been communicated accurately and that committee members are adequately prepared for the next meeting.
- 5. The contractor shall facilitate plenary and work group sessions (face-to-face meetings and conference calls, as needed) of the CHPAC. As facilitator, the contractor shall assist participants in articulating their interests, identifying areas of agreement, and developing consensus solutions to the problems that divide them. As facilitator, the contractor shall keep the parties talking, listening, and moving as much as possible towards the goal of the process. The contractor, in consultation with the WA-COR and DFO, shall organize and facilitate meetings with the CHPAC Steering Committee, including developing agendas and arranging conference call logistics. THE FACILITATOR SHALL NOT TAKE A POSITION ON THE MERITS NOR RECOMMEND TO THE PARTIES WHAT THE SUBSTANTIVE RESOLUTION OF AN ISSUE SHOULD BE.
- 6. The contractor shall provide meeting summaries of CHPAC plenary and work group meetings, conference calls, and subcommittee meetings to the OCHP WA-COR, the DFO, and the committee members. The meeting summaries shall include agreements, outstanding issues, action items, and work assignments. The summaries shall not include attributions except for clarification or assignment of work. The facilitator shall distribute final meeting summaries to the WA-COR and DFO, committee members and other participants.
- 7. As determined through consultation with the WA-COR and DFO, the contractor shall provide subject matter experts in the field of pediatric medicine, developmental disorders, pediatric oncology, communications, economics, childhood unintentional injuries, and other relevant disciplines as identified by OCHP under procedures described in the base contract for approval of subcontractors and consultants. The subject matter expert shall perform the following tasks:
 - a) Provide expert testimony, briefings, presentations, literature searches, or discussions with the CHPAC or OCHP.
 - b) Write scientific issues papers to provide information in specific areas, and
 - c) Other tasks as identified by OCHP and agreed to by the OCHP WA-COR.
- 8. The contractor shall provide meeting facilities, meeting set-up, full meeting implementation, and full administrative and technical support including preparation of pre-meeting materials, meeting materials, logistic and travel materials, name tags, name tents, post-meeting materials, audio-visual, and other needed equipment for all meetings of the plenary group and work groups for the CHPAC. The contractor shall consult with WA-COR OCHP DFO on the selection of meeting facilities and meeting materials.
- 9. Only to the maximum extent legally permissible, the contractor shall determine the travel logistics for CHPAC members by obtaining the members' travel itineraries, and transmitting the itineraries to OCHP for processing the travel authorizations.

- 10. The contractor shall furnish a draft final report of these efforts of the above listed activities to the EPA WA-COR. The contents shall include:
 - (a) Final meeting summaries with relevant and necessary attachments including lists of public observers.
 - (b) Copies of documents compiled by or agreed upon by the committee (ground rules, agreements, statements, fact sheets, etc).
 - (c) Mailing list for the CHPAC and alternates and any other mailing list(s) kept for communication purposes by the facilitators.
 - (d) Relevant substantive correspondence between the facilitator and the participants.
 - (e) A one page sheet summarizing the final budget for each of the projects. The budget shall be broken into two main categories: labor and other direct costs (ODC). The labor category shall show the number of hours of labor and resultant costs for each labor category. The labor category shall be subdivided into convening and negotiation phases where the project covered both phases. The other direct costs shall show the total costs for travel of facilitation team, participant or speaker travel (where incurred), communications costs (deliver, phone, fax, mail), meeting room and equipment costs, consultation costs (where incurred). The cumulative monthly report for the last reporting period or the final invoice if it summaries the total costs of the project as described above can be used for this purpose.
 - (f) An annual process evaluation by the facilitator summarizing results of the effort, analysis of issues and balance of parties, procedural lessons learned, and recommendation for improvements in the process.
- 11. The OCHP WA-COR will review the draft final report and provide comments and revisions as necessary. The contractor will prepare the final report incorporating their comments and revisions. The contractor shall provide the final report to the WA-COR.
- 12. The contractor shall make meeting materials available to CHPAC members electronically via an FTP site or other means.

Deliverables:

- 1. Meetings agendas provided to meeting participants as close to final as possible two weeks prior to meetings.
- 2. Final meeting materials one week prior to meetings.
- 3. Final meeting summaries two weeks after receipt of comments.
- 4. The contractor shall arrange for the participation of subject matter specialists in the disciplines listed above (#6) identified by OCHP for presentations at committee meetings as speakers, presenters, panelists.
- 5. Final report two weeks after receipt of comments.

VII. Reports

- 1. The contractor shall send EPA all reports in accordance with the terms of the basic contract.
- 2. Copies of all reports, meeting notices, agenda, summaries and any other written deliverables shall be sent to the WA-COR listed below. If oral briefings are scheduled for EPA staff, the DFO and the EPA WA-COR shall be notified in time to attend.
- 3. All reports shall be provided first in draft form. Upon receipt of comment from the WA-COR, the

contractor shall revise the report and distribute final copies as stated in the scope of work.

VIII. Management Controls

Periodic meetings between the EPA and Contractor's WA-CORs are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WA-COR's discretion, these meetings may occur via teleconference or video conferences. The Contractor shall document these meeting and submit copies of this correspondence to the EPA WA-COR. The EPA W-COR may identify one or more EPA technical representatives for this work assignment. Interaction between the Contractor and any EPA technical representative(s) designated by the WA-COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. These interactions do not result in technical direction to the contractor.

IX. Deliverables

Schedule

Conference Call Oral convening Reports Final Meeting Agendas Mail (or email) out of meeting materials Final Meeting summaries

Final Report of Process

Due No Later Than:

3 days after award Weekly after declaration of need

Three (3) weeks before meetings, post to website

Two (2) weeks before meetings

Two (2) weeks after receipt of comment Two (2) weeks after receipt of comment

X. <u>Milestones</u>:

Two or three (2) two-and-a-half-day CHPAC meetings.

Up to fifteen conference calls

Initial planning for CHPAC meeting

Ongoing coordination with the DFO and oversight/monthly reports

Conference calls with DFO and organization for future CHPAC work

XI. EPA Contacts:

WA-COR:

Martha Berger

Office of Children's Health Protection

MC: 1107A

Environmental Protection Agency 1301 Constitution Avenue, NW

Washington, DC 20460 Phone: (202) 546-2191

Alternate WA-COR:

LaVonne Switzer (202) 564-2711

	EP	PΑ	Unite		gton, DC 20460			Work Assignme	nt Num	ber		
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	United States Environm	nental Protection A	Agency		Work Assignment Nu	umber			
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Contract Number	Contract Period 11/	/01/2013 To	10/31/2	2015	Title of Work Assignr	nent/SF Site Nan	ne		
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Project Officer Name Melissa Reve	ely-Wilson				ch/Mail Code:				
Phone Number: 703-347-8523									
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PERFORMANCE WORK STATEMENT Work Assignment # 67

TITLE: Support for the Region 3 Workshop on Lead (Pb) in Urban Soils

Specify Section & Paragraph SOW: (select all that apply) (1) Dissemination of Information, (2) Preparation of Technical Publications, (3) Preparation of Electronic Products, and (4) Logistical and Technical Support for the Conduct of Meetings. (5) OTHER REQUIREMENTS

PERIOD OF PERFORMANCE: Award to October 31- 2015

BACKGROUND

As a component to ORD's Superfund and Technology Liaison (STL) Program, ORD is assisting with the sponsorship and planning of this workshop. Bill Hagel (Region 3 STL) is working with Jack Kelly, Region 3 On-Scene Coordinator in planning this workshop. We anticipate that approximately 60 people will attend in person and another 40-50 will participate by webinar. Most in person attendees will be from the eastern United States. They will include staff from Federal agencies, state and local governments, project managers, researchers, practitioners, and government-hired private consultants. We will invite technical speakers employed both within and outside of government service.

PURPOSE

The purpose of this Work Assignment is to obtain services and support to plan, organize, and document specific activities for a Pb in Urban Soils workshop to be held at EPA Region 3 office in Philadelphia, PA. Region 3 will hold this 2-day workshop to bring together researchers and practitioners who perform site assessment and cleanups at Pb contaminated urban sites and are investigating public health issues associated with soil Pb contamination in urban environments. The workshop will be held in the Region 3 Training Facility in the EPA Region 3 office. Short, topic-specific presentations (~15 minutes) will be provided initially to construct a framework for discussion. Each speaker will be instructed to address a series of questions prepared by the workshop planners. If time permits, and depending on audience interest, additional issues may be debated (e.g. urban gardening). Region 3 plans to utilize Webinar technology (such as Adobe Connect) for this event to allow for greater participation. The workshop is planned for September 15 & 16, 2015.

TASKS

Task 1. Prepare Work Plan and Cost Estimate

The Contractor shall prepare a Work Plan and Cost Estimate, including the proposed level of effort, cost plus fixed fee, and a schedule of tasks within 20 calendar days of the date of receipt of this SOW, and submit it to the Work Assignment Contracting Officer Representative (WA COR), the Project Officer, and the Contracting Officer for their respective approvals.

Task 2. Workshop Arrangements

The Contractor shall participate in organizational teleconferences (assume 7 one hour calls) on dates and times as indicated by the WA COR. The Contractor is to take notes on these calls and provide a written summary of the meeting minutes to the WA COR via e-mail within 5 business days.

Task 3. Speaker Travel

The Contractor shall assist with travel arrangements for up to 8 invited non-federal employee speakers, panel members and / or session chairs. The qualifications and attributes for each key participant are below:

• Knowledge and experience on issues relevant to lead (Pb) in urban soils chemistry, characterization, monitoring, risk, cleanup, and research.

Task 4. Pre-Meeting Materials

This will be billed as a "green" workshop, and therefore will have very few paper handouts. The Contractor shall compile material for an <u>electronic</u> pre-workshop packet posted online (by EPA).

Materials for the pre-workshop packet shall include a draft agenda, background materials, a logistical fact sheet (to include hotel and travel info and to be prepared by the Contractor), and available summaries of speaker presentations (PowerPoint format), speaker abstracts and biographies, and a list of all registrant email addresses. The Contractor shall provide the WA COR with the pre-meeting packet materials approximately one month prior to the workshop (electronically).

The Contractor, as directed by the WAM, shall assist EPA in monitoring the preparation, receipt and final submittal of presentations. This includes periodically contacting forum presenters to ensure they are on schedule in preparing and submitting their presentations and reporting back to the planning committee on their progress.

Task 5. On-Site Meeting Activities

- a) The Contractor shall make one person available at the EPA Region 3 facility during the dates of the workshop.
- b) The Contractor shall use an EPA-provided laptop and LCD monitor and load all PowerPoint presentations on the laptop and ensure that the projection video equipment is working during the workshop.
- c) The Contractor shall assist with on-site registration, which includes signage, tables, simple nametags, sign-in sheets, etc.
- d) The Contractor shall take abbreviated notes during the workshop and identifying any action items which will be used as part of the proceedings package.
- e) The Contractor will provide, distribute and collect all evaluation forms from attendees during the workshop, compile, and incorporate them into the edited proceedings (Task 6).
- f) The Contractor will assist the WAM in any day of workshop support necessary, including coordination with facility staff, to ensure the smooth execution of the workshop.

Task 6. Preparing and Editing the Workshop Proceedings

Within 30 working days following the workshop, the Contractor will produce a draft summary Proceedings report and submit it to the EPA WAM for review and comment. The draft and final Proceedings report shall be written in an organized and concise manner that follows EPA acceptable style guidelines, including consistent verb tense, style, font, and punctuation.

The Proceedings Packet will include the final forum summary report, final agenda, a list of registered participants, weblinks to the posted final versions of speaker presentations (PowerPoint format), a forum evaluation form (if used), and other materials as needed.

EPA will provide the Contractor with modifications, comments, and revisions that the Contractor shall incorporate into the final edited Proceedings report within 15 calendar days of receiving EPA's comments. At this time, the Contractor will also incorporate the final agenda, a summary of the forum evaluation forms, speaker abstracts and bios, the list of registrants, and their email addresses into the report.

Draft and revised Proceedings shall be provided to EPA in electronic format as an MS Word document.

DELIVERABLES

Task	Completion Date					
1. Performance Work Statement	Within 20 days after receipt of this Statement of Work, the					
	contractor shall provide a cost estimate.					
2. Workshop Arrangements	Within 3 days after work assignment approval, the Contractor					
	shall participate in a kickoff conference call (NTE 2 hours).					
	Subsequent to that, there will be regular periodic planning					
	calls, approximately 10, whereby the Contractor is to take					
	notes and provide a written summary of the meeting minutes					
	within 5 business days.					
3. Speaker Travel	No later than 14 calendar days after non-federal speakers,					
	panel members and/or session chairs have been identified by					
	the EPA Planning Team, the Contractor shall assist with					
	travel arrangements for those speakers. This may include					
	contacting the targeted speakers to secure travel cost					
	estimates and preparing any necessary internal paperwork					
	necessary to ensure those speakers are properly reimbursed					
	for their travel, lodging and other allowable costs.					
4. Pre/Post Meeting Materials	No later than 30 calendar days before the approved date of					
	the workshop, the Contractor will assemble and provide an					
	electronic version of the contents of the pre-meeting package					
	to the EPA WAM.					
5. On-Site Workshop Activities	The Contractor shall provide support (1-person) for the					
	registration of participants at the workshop. This may					
	include signage, tables, nametags, sign-in sheets, etc.					
6. Proceedings Preparation	Within 30 calendar days following the workshop, the					
	Contractor shall prepare the draft Proceedings report. Within					
	15 calendar days after receiving EPA's modifications,					
	comments and revisions, the Contractor shall incorporate					
	EPA's modifications, comments, and revisions into a final					
	Proceedings report in Word and Adobe PDF formats.					
7. Report of Work	The Contractor shall develop and submit reports of work as					
	required by the governing contract for this Work Assignment.					

CONFLICT OF INTEREST

The contractor shall disclose any conflict of interest regarding this work.

ACCEPTANCE CRITERIA

Deliverables shall be provided to the EPA WA COR in accepted Agency format and be of high quality. Deliverables shall be prepared using software compatible with current ORD computer systems. Deliverables shall be submitted electronically to the EPA WA COR via e-mail as well as hard copy (when requested).

MANAGEMENT CONTROLS

Technical direction for this Work Assignment is provided by this statement of work, by the work plan developed to implement this Work Assignment by the contractor (after it has been accepted and approved by the EPA WA COR), and by the contractor's designated management representatives. Periodic meetings and emails between the EPA and contractor Work Assignment managers are encouraged to discuss any questions that may arise during performance or completion of this Work Assignment. These meetings may occur via teleconference or video conferences. The Contractor shall document these meetings and submit copies of this correspondence to the EPA Project Officer (PO) and the WA COR.

The Contractor shall meet (conference call) with the WA COR to present and discuss the work plan for this Work Assignment before it is approved. With the exception of the WA COR and the PO, EPA personnel are not authorized to provide technical direction to the Contractor.

The WA COR may identify one or more EPA technical representatives for this Work Assignment, typically the DFO. Interaction between the contractor and any EPA technical representative(s) designated by the WA COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this Work Assignment. These interactions do not result in direction to the Contractor.

WORK ASSIGNMENT CONTRACTING OFFICE REPRESENTATIVE (WA COR): Bill Hagel, 215-814-3053, hagel.bill@epa.gov

ALTERNATE WA COR: Jack Kelly, 215-814-3112, kelly.jack@epa.gov

EDA	United States Environmer Washingto	ntal Protection Agency on, DC 20460		Work Assignment Number 1-67				
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			Phone	Phone Number 215-814-3053				
(Signature)		(Date)	FAX	FAX Number:				
Project Officer Name Melissa Rev	ely-Wilson		Brand	Branch/Mail Code:				
	Phone	Phone Number: 703-347-8523						
(Signature)	FAX	FAX Number: 703-347-8696						
Other Agency Official Name				Branch/Mail Code:				
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Work Assignment Manager Name Mich	ael Broder				Bra	Branch/Mail Code:			
					Pho	Phone Number 202-564-3393			
–					FAX	FAX Number:			
Project Officer Name Melissa Revely-Wilson				Bra	Branch/Mail Code:				
					Pho	Phone Number: 703-347-8523			
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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001

WA 1-68

TITLE: Technical Editing and Revision Support of Risk Assessment Forum Documents

Specify Section & Paragraph SOW: A. Assessment Issues and Documents

PERIOD OF PERFORMANCE: CO award to 10/31/15

A. BACKGROUND

Federal regulatory agencies often rely on risk assessments as a primary component in their decision-making process. To ensure that assessments are conducted in a consistent and transparent manner the Environmental Protection Agency develops guidelines, guidance documents and "white papers" to provide a framework for analyzing data. EPA's Risk Assessment Forum (RAF) is charged with coordinating the development of Agency-wide guidelines and guidance documents that provide that framework. The principal audience for these products are EPA risk assessors and risk managers; however, these documents also provide clarity and transparency to the stakeholders and other interested parties, and are often cited by other regulatory entities.

B. PURPOSE

As noted above, guidelines and related products are among the most important products generated by EPA. The intent of these products is to inform risk assessors how to acquire data and apply it to risk assessments; and to promote consistency in Agency risk assessments and inform stakeholders and other interested parties of EPA risk assessment policies and practices. As such, these documents need to be written in a clear and concise manner.

The first step in document revision and editing is monitoring discussions among the technical panel to identify changes to the document. Following those meetings the technical panel will revise the document and the document will be submitted to the Contractor for technical editing.

Technical editing follows the development of the content and subsequent revision to improve the clarity of the message. This assignment is intended to ensure consistency throughout the document in content and voice, avoid redundancy, and above all, ensure that the information is clearly and accurately presented. Depending upon the intended audience it is important that the document communicate at the appropriate level of sophistication. For the most part the document needs to primarily inform risk assessors of the Agency's methods and policies when performing assessments for the Agency but also communicate to other stakeholders.

This work assignment will serve as a generic task with the intention that it will cover support for the revision and technical editing of several documents for which technical direction will be issued for each product. The technical direction accompanying each document will contain instructions specific to the product.

C. KNOWLEDGE AND SKILLS REQUIRED

Although much of the content has been provided, it is essential that the contractor possess demonstrated experience in the production of quality EPA guidelines with an appropriate level of expertise in exposure science, human health and ecological risk assessment methods, to adequately critique and edit RAF documents for clarity and consistency, as well as providing grammatical editing. The contractor shall be competent in

tracking meeting discussions and taking meeting notes. The level of expertise for each task will be commensurate with the technical direction.

D. TASKS

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the COR, workgroup members, and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks for the work assignment. Similarly, the Contractor shall initiate communication with the COR within three days of the issuance of a technical direction. The contractor shall initiate additional communication with the COR should developments arise that will affect the conduct or schedule of the assignment.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in the technical direction under this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan that shows assigned personnel by task and the qualifications of the proposed personnel.

The Contractor shall develop a QAPP for approval by the WAM and Quality Assurance Manager. The Contractor must address in the QAPP how they are going to consider the use of secondary data to carry out this task. Secondary data are defined as environmental or health data that were developed for a different purpose. This includes data used from citations found in the literature. See these documents: "EPA Manual C/0 2105-P-01-0: EPA Quality Manual for Environmental Programs (QAPP)"; "EPA Requirements for Quality Assurance Project Plans (QA/R-5)," http://www.epa.gov/quality/qs-docs/r5-final.pdf; and "A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information" and its Addendum, http://www.epa.gov/stpc/assess.htm. The QAPP shall be submitted simultaneously with the Work Plan for approval.

Task 3. Tracking Meeting Discussions

The Contractor shall participate in meetings as stated in the technical direction; take meeting notes on recommended changes to the document; record the changes in the compiled comments from reviewers and incorporate those changes in the document. The contractor shall update references, links, and hyperlinks consistent with the revisions per technical direction.

Task 4. Technical Editing

The Contractor shall review and edit the document addressing grammatical, syntax, and spelling errors that may exist in the document with specific attention to the items listed in the technical direction. The technical direction may also include associated activities such as tabulating reviewers' comments on draft documents. The Contractor shall maintain ongoing communication with the COR to ensure quality and timely completion of the project.

Task 5. Delivery of the Final Product

The Contractor may deliver electronic versions (MS Word 2013) of the edited document to the COR, alternate COR, and others designated in the technical direction including both clean and marked drafts: the latter shall be a revised document presented as a "track changes.

E. SCHEDULE AND DELIVERABLES

Product	Due Date
Task 1. Initial Conference Call	3 days after award
Task 2. Staffing Plan, and QAPP	Per contact requirements
Task 3. Attend and track meetings, taking notes. The contractor shall update	As specified in the technical
references, links, and hyperlinks consistent with the revisions per technical	direction
directions.	
Task 4. Shall review and edit the document addressing grammatical, syntax, and	As specified in the technical
spelling errors that may exist in the document with specific attention to the items	direction.
listed in the technical direction laid out in the attachment.	
Task 5. Shall deliver an electronic version (MS Word 2013) of the draft document	As specified in the technical
to the COR, alternate COR, and others designated in the technical direction	direction.
including each in both clean and marked-up drafts: the latter shall be a revised	
document presented as a "track changes unless otherwise specified in the technical	
direction.	

F. Acceptance Criteria

Final products shall be produced by the Contractor upon the EPA WA COR's approval through written technical direction. The Contractor shall provide all materials written as part of these tasks to the EPA WA COR, as per work assignment, in electronic format. Electronic versions shall be in MS Word 2013, PowerPoint 2013 and Excel 2013 computer format as specified in the technical direction.

G. MANAGEMENT CONTROLS:

Periodic meetings between the EPA and contractor work assignment managers are encouraged to discuss any questions that may arise during performance or completion of this work assignment. At the EPA WA COR's discretion, these meetings may occur via teleconference or video conferences. The contractor shall document these meetings and submit copies of this correspondence to the EPA WA COR.

The EPA WA COR may identify one or more EPA technical representatives for this work assignment. Interaction between the contractor and any EPA technical representative(s) designated by the EPA WA COR is solely for the purpose of presenting and discussing the information, analyses, results, or presentations related to this work assignment. The interaction will be technical communication vice technical direction. Per the technical direction clause EPAAR 1552.237-71 of the contract, the EPA PO COR and the EPA WA COR or alternate EPA WA COR are the only representatives of the CO authorized to provide technical direction.

Per the technical direction clause, the CO and PO will be provided with copies of all technical direction.

H. CONFIDENTIALITY

Some of the information to be edited under this task may be internal information that is not ready for public distribution. The Contractor shall not discuss the contents of the document with anyone not specified as a participant in the document review process or its preparation.

VI. MANAGEMENT CONTROLS

1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.

2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Michael W. Broder Office of Science Advisor U.S. EPA (8105-R) Office of the Science Advisor 1200 Pennsylvania Avenue, N.W. Washington, D.C. 20460

Telephone: (202) 564-3393 Fax: (202) 564-2070

Alternate Work Assignment COR:

Lawrence Martin Office of the Science Advisor U.S. EPA (8105-R) 1200 Pennsylvania Ave., NW Washington, DC, 20460 Telephone (202) 564-6497

Fax: (202) 564-2070

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				Pho	Phone Number: 513-487-2852			
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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 1-69

TITLE: Scientific and Technical Editing and Writing for the Safe and Sustainable Water Resources Research Program

Specify Section & Paragraph SOW: A. Assessment Issues and Documents 1. Human Health Assessment Documents; E. Risk Assessment Support; F. Information Management

PERIOD OF PERFORMANCE: Award to October 31, 2015

I. PURPOSE

The purpose of this Work Assignment (WA) is to provide the U.S. Environmental Protection Agency's (EPA) Immediate Office of the Assistant Administrator (IOAA), Office of Research and Development (ORD), scientific and technical editing and writing support to the Safe and Sustainable Water Resources (SSWR) Research Program.

II. BACKGROUND

Essential for all life, water is the only substance found on Earth naturally in three forms: solid, liquid and gas. Human life, and many plants and animals, depend on freshwater; however, available sources are surprisingly miniscule–0.007 percent–compared with Earth's total amount of water. Water is not only essential for human health and well-being and all types of ecosystems (freshwater, brackish, saline), but is vital for a robust economy. Water is needed for the production of many goods and services, for example, agriculture, energy, manufacturing, transportation, commercial and recreational fishing, tourism and others. As the interchange of water through the hydrologic cycle is continually dynamic, so are the changing spatial and temporal demands on water quantity and quality for various uses.

The EPA's SSWR research program provides the scientific results and innovative technologies that are needed to protect the chemical, physical and biological integrity of the Nation's waters and to ensure safe drinking water and water systems.

The SSWR research program uses an integrated systems approach to purpose-driven, state-of-the-art research to support innovative scientific, technological and behavioral solutions that ensure clean, adequate and equitable supplies of water to support human health and well-being and resilient aquatic ecosystems. The focus of our research is on the highest-priority, current and long-term water resource challenges to inform EPA's regulatory and non-regulatory decisions and implementation needs, and translating research findings to support communities, states and tribal partners. The overarching watershed approach to our drinking water, wastewater, stormwater and ecosystems research recognizes the dynamic 'one water' hydrologic cycle.

Integrated throughout the program are the goals of a sustainable environment, economy and society and the overarching drivers of changing climate, extreme events, land use, energy, agriculture and demographic scenarios.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan, Staffing Plan, and Quality Assurance Project Plan (QAPP)

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The contractor shall be responsible for integration, compilation, drafting and/or editing text to be used by EPA for various materials, including the program's research plans, project summaries, responses torequests for proposal announcements, internal and external program briefings, communications and others. In all assignments under this WA, the contractor shall conform to guidance under Section VII below. Assignments will vary in the level of user readability, ranging from highly technical translated scientific and technical information to text more appropriate for a broader range of stakeholders and education.

The contractor shall maintain communication with the COR through weekly phone calls or email updates and attend meetings of the SSWR team as necessary. Due to the nature of the work being requested, technical clarification from the COR will be required. All technical clarification shall be documented by both the COR and contractor. The contractor shall ensure that all tasks are progressing on schedule and are delivered by the deadlines agreed upon by the COR, technical contact and the contractor.

No data will be generated as a result of this WA so a QAPP is not required

Task 3: Prepare SSWR materials.

The contractor shall be responsible for integration, compilation, drafting and/or editing text to be used by EPA for various materials including the program's research plans, project summaries, request for proposal announcements, briefings, communications and others. Tasks will vary in the level of user readability, ranging from highly technical translated scientific and technical information to text more appropriate for a broader range of stakeholders and education. The contractor may also suggest additional contributions to the writing process as required, including literature review and synthesis.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan, and QAPP	Per contract requirements
Task 3. Prepare SSWR materials	In accordance with Technical Work Plan prepared under
	Task 2

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

Patricia McGhee

Telephone: 919-541-2607

Fax: 919-685-3607

e-mail: mcghee.patricia@epa.gov

Mailing Address:

U.S. Environmental Protection Agency

MD E205-09 Research Triangle Park, NC 27711

Overnight Delivery location: U.S. EPA MD E205-09 4930 Old Page Road Durham, NC 27703

Alternate Work Assignment Manager:

Melissa McCullough Telephone: 919/541-5646

e-mail: loughran.michael@epa.gov

Mailing Address: USEPA Headquarters William Jefferson Clinton Building 1200 Pennsylvania Avenue, N. W. Mail Code: 8101R Washington, DC 20460

Overnight Delivery location: Ronald Reagan Building 1300 Pennsylvania Ave., N.W. Rm # 41274 Washington, DC 20004

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				Phor	Phone Number 919-541-3896				
(Signature)	FAX	FAX Number:							
Project Officer Name Melissa Revely-Wilson					ch/Mail Code:				
					ne Number: 703-	347-8523			
(Signature) (Date)					Number: 703-3	847-8696			
Other Agency Official Name					ch/Mail Code:				
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Contracting Official Name Adam Me:	ier				Branch/Mail Code:				
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PERFORMANCE WORK STATEMENT CONTRACT NO. EP-C-14-001 WA 1-70

<u>TITLE</u>: Completion of Exposure-Response Training and Recommendations for Best Practices Documents

Specify Section & Paragraph SOW: Please select from the following:

E. Risk Assessment Support, Paragraph 1. Science Writing, Risk Communication and Training

PERIOD OF PERFORMANCE: CO approval through 10/31/2015

I. PURPOSE

The purpose of this Work Assignment is to provide services to the U.S. Environmental Protection Agency's (hereinafter EPA or Agency) National Center for Environmental Assessment (NCEA), Office of Research and Development (ORD), in bringing to completion the draft training materials (WA 4-43) and a related Recommendations for Best Practices document initially developed under Contract EP-C-09-009. These documents were never completed due to sequestration and the ensuing Government shutdown.

II. BACKGROUND

The Integrated Risk Information System (IRIS) is an EPA database containing Agency consensus scientific positions on potential adverse human health effects that may result from chronic (or lifetime) exposure to chemicals in the environment. IRIS currently provides information on over 500 specific chemical substances and the potential adverse health effects that may result from exposure to each. In addition to the IRIS assessments, NCEA also develops the Integrated Science Assessments (ISAs) that are used in support of the National Ambient Air Quality Standards (NAAQS) for six priority pollutants.

The IRIS assessments include development of reference dose (RfD) and reference concentration (RfC) values for noncancer health effects, along with cancer slope factors and inhalation unit risk estimates for cancer. Among the recommendations from the Risk Assessment Forum in a review of the RfD/RfC process (EPA/630/P-02/002F, available online at http://www.epa.gov/raf/publications/pdfs/rfd-final.pdf) was development of graphical arrays of the dose-response information available for the various health effect endpoints associated with a chemical of interest. The intent was for such graphical presentations of the data to be useful in comparing results between studies and between endpoints. Although the graphics developed to meet these recommendations were originally directed toward the IRIS process, they have also more recently been generated for use in the ISAs and have been used by the National Homeland Security Research Center (NHSRC) in the technical support documents for their Provisional Advisory Levels (PALs). Similar arrays have also been developed and are included in the Technical Support Documents for the Acute Exposure Guideline Levels (AEGLs) and by ATSDR in their Toxicological Profiles.

At present, the incorporation of exposure-response arrays into assessments has been sometimes limited and often inconsistent. NCEA organized a working group to look across the Agency and with partner Agencies on the best practices being used in development of exposure response arrays, provide guidance on methods for development and most effective format options, with the final goal of creating a set of recommendations for

development of these arrays. A one-day, on-line workshop was held on October 24, 2011 with the relevant stakeholders where a number of recommendations and proposed follow-on activities were discussed, one of which was to develop a document on Recommendations of Best Practices for developing Exposure-Response Arrays. More recent work on the IRIS Handbook has led to additional guidance which EPA would like to also have incorporated into this effort. This Work Assignment is designed to support finalizing the "Recommendations" document and complete the training materials developed previously to assist in applying exposure-response and similar graphic elements into NCEA risk documents.

III. STATEMENT OF WORK

Task 1: Establish Communication

Within 3 days of start date of this WA, the Contractor shall schedule a conference call (not to exceed 1 hour) with the WAM and appropriate contractor staff to clarify outstanding questions and confirm the schedule and specific tasks.

Task 2: Work Plan and Staffing Plan

The Contractor shall prepare a Technical Work Plan describing how the work outlined in this Performance Work Statement will be performed, including deliverables, a schedule, budget, and level of effort. The Contractor shall also prepare a Staffing Plan, which shall be submitted as part of the Work Plan, which shows assigned personnel by task and the qualifications of the proposed personnel. The Contractor shall provide expertise in the basic science areas of toxicology, pharmacology, physiology, chemistry, epidemiology, human health risk assessment, and statistics. A working knowledge of risk assessment methodology and EPA risk assessment guidelines is required.

The Contractor shall not perform any work on subsequent tasks under this WA until the Work Plan is reviewed and approved.

Task 3: Completion of Exposure-Response Array Training Materials

The contractor shall work in coordination with the WAM in the refinement and continued development of the Exposure-Response Array training materials. This product was initiated in WAs 3-43 and 4-43 under Contract EP-C-09-009. The training materials include presentation materials, instructor notes, reading packets, exercises and examples which are organized into five modules. Completion of individual modules and the priority order of those completions is anticipated to be in this order (subject to discussion and final decision by the WAM): Module 1 – Introduction; Module 2 – Prototype; Module 5 – Summary Arrays; Module 3 – Array Builder; and Module 4 – Metadata Viewer. These training materials will be developed to be compatible with and amenable to incorporation into the RATE Program. After discussion with the WAM, the contractor will propose steps for implementing this task, with estimated time lines and LOE. After review and further discussion, EPA may approve the plan or portions of it, and may amend the work assignment if that is necessary to accommodate changes in scope and LOE.

Task 4: Finalize Recommendations for Best Practices Document

The contractor shall work in coordination with the WAM in the refinement and continued development of the draft Recommendations Document from materials developed in prior work assignments (WAs 2-43, 3-43 and 4-43 under Contract EP-C-09-009), including the summary from an October 2011 workshop. These refinements

are expected to lead to a final EPA report which can be used as a reference for the IRIS Handbook as well as to the training materials being developed/completed in Task 3 of this work assignment.

IV. ANTICIPATED DELIVERABLES

All products by the Contractor must be of high quality, written in a clear concise style, with a logical organization and presentation. Deliverables shall be provided to EPA in electronic formats compatible with EPA-supported software (e.g., Excel spreadsheets, Word documents, BMDS accessory files [*.(d), *.out, *opt, *.ssn]).

V. DELIVERABLES AND SCHEDULE

Task 1. Initial Conference Call	3 days after award of Work Assignment
Task 2. Staffing Plan	15 days after award
Task 3. Revised Training Materials	60 days after award
Task 4. Final Recommendations Document	90 days after award or October 15, 2015, whichever occurs first

Note: All days are calendar days.

VI. MANAGEMENT CONTROLS

- 1. All deliverables shall be reviewed for conformance to the requirements of this work assignment before being approved as final.
- 2. The contractor shall comply with other applicable requirements for final work assignment reports stipulated in contract.

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS PROJECT

Guidance is strictly limited to technical and analytical support. The contractor shall not engage in activities of an inherent governmental nature such as the following:

- (1) Formulation of Agency policy
- (2) Selection of Agency priorities
- (3) Development of Agency regulations

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the PO, WAM or CO

VIII. SPECIAL CONDITIONS AND ASSUMPTIONS

The contractor shall hold a conference call with the EPA WAM at the initiation of the work assignment, and shall provide a bi-weekly update to the WAM by telephone for the duration of the work assignment, in addition to the standard reporting requirements of the contract.

IX. EPA CONTACT INFORMATION

Copies of all correspondence pertaining to the performance of this work assignment shall be sent to the PO.

Work Assignment Manager (WAM):

George M. Woodall, PhD NCEA (MD B243-01) RTP, NC 27711 (919) 541-0413 FAX (919) 541-0245 woodall.george@epa.gov

Alternate WAM:

James Weaver, PhD NCEA (MD B243-01) RTP, NC 27711 (919) 541-1545 weaver.james@epa.gov

Appendix A

Quality Assurance Instructions for Contractors Citing Secondary Data

Section 515 of the Treasury and General Government Appropriations Act for fiscal year 2001 directed the Office of Management and Budget (OMB) to issue guidelines to all Federal agencies to ensure and maximize the quality, objectivity, utility, and integrity of the information they disseminate. This law and the OMB guidance subsequently issued in 67 FR 8452 (02/22/02) underscore the need for EPA/NCEA to assess the quality and credibility of the secondary research information cited in its assessment documents.

Secondary research information is defined as information that was originally produced for one purpose but is now being recompiled or reassessed for a different purpose. Secondary research information usually originates from such primary sources as journal articles, books, government and industry reports, databases, and models. The set of processes that follows serves as a guide to evaluate the strength of secondary data gathered from these primary sources.

The Contractors must list the sources for the references cited in his/her document chapters or sections. The source list will include but not be limited to the names of any commercially available or local databases searched by computer or by hand, the search terms and search strategy used, and the time period of the search. List any print sources like books or journal articles which provided references. List any sources of raw data.

After fully reporting all of the reference sources, identify the most relevant information or key studies among the references you cite and critically evaluate them. Key studies are those most crucial or pivotal to answer the research questions for the project. The key study may have positive or negative results and may even be all that is currently available on the research topic, but the key study is integral to any discussion of the topic. Sometimes, the key study is not recognizable until all of the literature is gathered and evaluated. Key studies should exhibit at least most of the general attributes defined below:

FOCUS: the work not only addresses the area of inquiry under consideration but also contributes to its understanding;

VERIFY: the work is consistent with accepted knowledge in the field or, if not, the new or varying information is documented within the work; the work fits within the context of the literature and is intellectually honest and authentic;

INTEGRITY: Is the work structurally sound? In a piece of research, is the design or research rationale logical and appropriate?

RIGOR: the work is important, meaningful, and non-trivial relative to the field and exhibits sufficient depth of intellect rather than superficial or simplistic reasoning;

UTILITY: the work is useful and professionally relevant; it makes a contribution to the field in terms of the practitioners' understanding or decision-making on the topic.

CLARITY: Is it written clearly and appropriately for the nature of the study?

Use the check list on the following page to evaluate the key studies.

DATA CHECKLIST FOR EVALUATING A STUDY

1.)	Bibliographic identification of the study.
	Study Identifiers: Author(s): Title: Study Citation: Storage location (e.g., library, facility archive, personal archive):
2.)	Why is the study key to the particular project? (For example, is the study an example of new research or confirmation of previous work? Is the study's population larger or followed for a longer period of time than before, is the methodology better than other studies or corrective of problems in previous studies, or do the results provide new insight into the problem?)
3.)	Summarize the study structure and methodology. What sampling techniques and statistical tests are used?
4.)	Potential problem areas in the study; consider: study design, factors occurring within and outside of the study which may affect its validity, sampling errors, and any other perceived weaknesses.
5.)	Do any data used from sources outside of the study seem reliable and generally free of measurement error? Discuss and give examples.
6.)	Evaluate the study in terms of the appropriateness of the analytical methodology. In responding, consider the following questions:
	Are research questions clearly stated; dependent and independent variables clearly defined?
	Do the authors explain the type of data obtained from measures of the variables?
	Are statistical methods adequately described; are they justified?
	Is a source provided for the any statistical software used to analyze the data?
	Is the purpose of the analysis clear?
	Are any scoring systems described?
	Are potential confounders adequately controlled for in the analysis?
	Are analytic specifications of the variables consistent with the evaluation questions or hypotheses under study?
	Is the unit of analysis specified clearly?

If statistical tests are used to determine comparability or difference, are p values provided; is the practical significance of these findings, as contrasted with the statistical significance, discussed?

7.) Evaluate the study's results. Consider the following questions:

Are study questions (objectives, hypotheses) clear?

Are all study questions answered?

Are negative findings presented?

Are missing data explained?

Are text and tables, figures, and graphs consistent?

8.) Evaluate the study's conclusions. Consider the following questions:

Are the conclusions based on the study's data in that findings are applied only to the sample that was included in the research?

When the authors compare their findings with those from another study, do the authors demonstrate the similarity of the two studies?

Does the author discuss limitations of design, sampling, data collection, etc.?

To what extent do the limitations affect one's confidence in the conclusions?

9.) How strong is the study, overall; relative to other similar studies? Do its weaknesses jeopardize its being a key study, or is it usable despite the reservations?

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